

US3552005 (Prod: Saint Louis University)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:04:59

All time stamps listed in this document are displayed in GMT

US3552005

Form: Participant Creation

Data signed: (b) (4) 21 Feb 2021 17:18:51

Generated On: 10 Jun 2021 08:04:59

Participant ID

US3552005

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

US3552005

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

Date of Informed Consent (<i>dd MMM yyyy</i>)	11 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 29 Mar 2021 13:55:28

Generated On: 10 Jun 2021 08:04:59

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 29 Mar 2021 13:55:28

Generated On: 10 Jun 2021 08:04:59

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 29 Mar 2021 13:55:28

Generated On: 10 Jun 2021 08:04:59

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 29 Mar 2021 13:55:28

Generated On: 10 Jun 2021 08:04:59

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 29 Mar 2021 13:55:28

Generated On: 10 Jun 2021 08:04:59

Condition	QUADRUPLE BYPASS
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2002
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2002
Stop Year (derived)	2002

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 29 Mar 2021 13:55:28

Generated On: 10 Jun 2021 08:04:59

Condition	TYPE 2 DIABETES
Start date (dd MMM yyyy)	UN UNK 1997
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1997
Start Year (derived)	1997
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 29 Mar 2021 13:55:28

Generated On: 10 Jun 2021 08:04:59

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 29 Mar 2021 13:55:28

Generated On: 10 Jun 2021 08:04:59

Condition	BENIGN CYST TESTICULAR
Start date (dd MMM yyyy)	UN UNK 1973
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1973
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1973
Start Year (derived)	1973
Stop Month and Year (derived)	JAN 1973
Stop Year (derived)	1973

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 29 Mar 2021 13:55:28

Generated On: 10 Jun 2021 08:04:59

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

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 29 Mar 2021 13:55:28

Generated On: 10 Jun 2021 08:04:59

Condition	L5 DISK HERNIATION
Start date (dd MMM yyyy)	UN UNK 1982
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1982
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1982
Start Year (derived)	1982
Stop Month and Year (derived)	JAN 1982
Stop Year (derived)	1982

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 29 Mar 2021 13:55:28

Generated On: 10 Jun 2021 08:04:59

Condition	C-3 DEGENERATIVE DISK DISEASE
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 29 Mar 2021 13:55:28

Generated On: 10 Jun 2021 08:04:59

Condition	T-3 DEGENERATIVE DISK DISEASE
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 29 Mar 2021 13:55:28

Generated On: 10 Jun 2021 08:04:59

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1965
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1965
Start Year (derived)	1965
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 29 Mar 2021 13:55:28

Generated On: 10 Jun 2021 08:04:59

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

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 29 Mar 2021 13:55:28

Generated On: 10 Jun 2021 08:04:59

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

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 29 Mar 2021 13:55:28

Generated On: 10 Jun 2021 08:04:59

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 AUG 2020
Time of assessment (00:00-23:59)	10:00 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 10:00
Height (xxx.x)	68.5 in
Weight (xxx.x)	218 lb
BMI (xxx.x)	32.73296 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 21 Feb 2021 17:20:33

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify CHURCH SERVICES 1X PER WEEK.

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 21 Feb 2021 17:20:33

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

What was the date of randomization? (dd MMM yyyy) 11 AUG 2020

What was the participant's randomization number? 185651

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 AUG 2020
Time of assessment (00:00-23:59)	10:00 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 10:00
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 AUG 2020
Time of assessment (00:00-23:59)	12:10 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 12:10
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

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) 11 AUG 2020

What was the treatment time? (00:00-23:59) 11:40 (24 HR)

Treatment Date and Time (derived) 11 AUG 2020 11:40

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 AUG 2020
Collection time (00:00-23:59)	10:49 (24 HR)
Collection date and time (derived)	11 AUG 2020 10:49

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

Collection date (dd MMM yyyy)			11 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:50	11 AUG 2020 10:50
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

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

11 AUG 2020 12:12

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 14:30

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	11 AUG 2020 16:13
PC Open Date & Time	11 AUG 2020 15:25
PC Close Date & Time	12 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

12 AUG 2020 12:02

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

13 AUG 2020 12:46

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:04:59

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

98.2 °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

14 AUG 2020 12:10

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:04:59

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

98.2 °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

15 AUG 2020 12:51

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 12:25

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 12:03

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

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

11 AUG 2020 12:13

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 14:30

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

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

11 AUG 2020 16:14

PC Open Date & Time

11 AUG 2020 15:25

PC Close Date & Time

12 AUG 2020 11:59

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:04:59

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

12 AUG 2020 12:02

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:04:59

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

13 AUG 2020 12:47

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:04:59

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

14 AUG 2020 12:10

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:04:59

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

15 AUG 2020 12:52

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:04:59

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

16 AUG 2020 12:25

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:04:59

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

17 AUG 2020 12:04

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 12:14
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 14:30

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 16:15
PC Open Date & Time	11 AUG 2020 15:25
PC Close Date & Time	12 AUG 2020 11:59

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:59

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 12:03
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

59 of 2784

EAB) (1725)

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:59

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 12:47
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:59

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 12:11
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:59

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 12:52
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

65 of 2784

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:59

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 12:26
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

67 of 2784

EAB) (1725)

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:59

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 12:04
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3552005

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552005

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552005

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3552005

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552005

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552005

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552005

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:20:34

Generated On: 10 Jun 2021 08:04:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3552005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 17:20:34

Generated On: 10 Jun 2021 08:04:59

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	7 SEP 2020
Time of assessment (00:00-23:59)	08:00 (24 HR)
Vital Signs Date and Time (derived)	7 SEP 2020 08:00
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3552005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 17:20:34

Generated On: 10 Jun 2021 08:04:59

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	7 SEP 2020
Time of assessment (00:00-23:59)	09:28 (24 HR)
Vital Signs Date and Time (derived)	7 SEP 2020 09:28
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3552005

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 17:20:34

Generated On: 10 Jun 2021 08:04:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 SEP 2020

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

US3552005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

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) 7 SEP 2020

What was the treatment time? (00:00-23:59) 08:48 (24 HR)

Treatment Date and Time (derived) 7 SEP 2020 08:48

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

US3552005

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	7 SEP 2020
Collection time (00:00-23:59)	8:20 (24 HR)
Collection date and time (derived)	7 SEP 2020 8:20

US3552005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

Collection date (dd MMM yyyy)			7 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:21	7 SEP 2020 08:21
Nasopharyngeal Swab 2	No		

US3552005

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 09:19

PC Open Date & Time

07 SEP 2020 09:08

PC Close Date & Time

07 SEP 2020 11:38

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.5 °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	07 SEP 2020 19:31
PC Open Date & Time	07 SEP 2020 12:33
PC Close Date & Time	08 SEP 2020 11:59

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

08 SEP 2020 12:47

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 12:12

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 12:20

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:04:59

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

98.0 °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

11 SEP 2020 14:12

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:04:59

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

12 SEP 2020 12:53

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

13 SEP 2020 13:11

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

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

07 SEP 2020 09:19

PC Open Date & Time

07 SEP 2020 09:08

PC Close Date & Time

07 SEP 2020 11:38

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

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

07 SEP 2020 19:33

PC Open Date & Time

07 SEP 2020 12:33

PC Close Date & Time

08 SEP 2020 11:59

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:04:59

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

08 SEP 2020 12:47

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:04:59

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

09 SEP 2020 12:13

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:04:59

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

10 SEP 2020 12:21

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:04:59

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

11 SEP 2020 14:12

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:04:59

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

12 SEP 2020 12:53

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:04:59

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

13 SEP 2020 13:11

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

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

No ☒

Yes ☐

PC Time stamp	07 SEP 2020 09:20
PC Open Date & Time	07 SEP 2020 09:08
PC Close Date & Time	07 SEP 2020 11:38

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

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

No ☒

Yes ☐

PC Time stamp	07 SEP 2020 19:34
PC Open Date & Time	07 SEP 2020 12:33
PC Close Date & Time	08 SEP 2020 11:59

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:59

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 12:48
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:59

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 12:14
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:59

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 12:21
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:59

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 14:12
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:59

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 12:54
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:59

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 13:12
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3552005

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3552005

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552005

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552005

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552005

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552005

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552005

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:20:34

Generated On: 10 Jun 2021 08:04:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3552005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 17:20:34

Generated On: 10 Jun 2021 08:04:59

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3552005

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 17:20:34

Generated On: 10 Jun 2021 08:04:59

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.

US3552005

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 17:20:34

Generated On: 10 Jun 2021 08:04:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 OCT 2020
Collection time (00:00-23:59)	08:56 (24 HR)
Collection date and time (derived)	2 OCT 2020 08:56

US3552005

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:20:34

Generated On: 10 Jun 2021 08:04:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 OCT 2020 07:35:44
Patient Cloud Open Date & Time	11 OCT 2020 00:01
Patient Cloud Close Date & Time	15 OCT 2020 23:59

US3552005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

21 OCT 2020 14:18:57

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3552005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

26 OCT 2020 16:41:22

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3552005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 NOV 2020 08:40:32
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3552005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 NOV 2020 08:30:49

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 NOV 2020 16:23:27

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 NOV 2020 20:26:51

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 DEC 2020 20:52:44

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 DEC 2020 12:49:27
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 DEC 2020 14:12:34

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 09:48:35

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 JAN 2021 09:19:53

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 JAN 2021 21:13:51

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 JAN 2021 20:44:20

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 JAN 2021 20:42:16
Patient Cloud Open Date & Time	21 JAN 2021 00:01
Patient Cloud Close Date & Time	25 JAN 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 JAN 2021 20:48:48

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 FEB 2021 07:57:23
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 FEB 2021 15:23:28

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 FEB 2021 13:59:19

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	25 FEB 2021 18:45:24
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 19:10:46

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 MAR 2021 08:31:14

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 MAR 2021 01:38:30

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 MAR 2021 06:57:43

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 20:47:25

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 APR 2021 12:56:01

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

Date and time of submission

16 APR 2021 20:12:35

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 21:28:37

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

Date and time of submission

30 APR 2021 20:40:52

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2021 00:01
Patient Cloud Close Date & Time	19 JUL 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 SEP 2021 00:01
Patient Cloud Close Date & Time	13 SEP 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 JAN 2022 00:01
Patient Cloud Close Date & Time	24 JAN 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 FEB 2022 00:01
Patient Cloud Close Date & Time	28 FEB 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 APR 2022 00:01
Patient Cloud Close Date & Time	25 APR 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

[Patient Cloud Open Date & Time](#)

25 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

[Patient Cloud Open Date & Time](#)

13 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3552005

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:04:59

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		08 MAR 2021 19:10:30

US3552005

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552005

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552005

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:20:32

Generated On: 10 Jun 2021 08:04:59

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552005

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:20:32

Generated On: 10 Jun 2021 08:04:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552005

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552005

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552005

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552005

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552005

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 03:06:55

Generated On: 10 Jun 2021 08:04:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3552005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 15:10:29

Generated On: 10 Jun 2021 08:04:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 FEB 2021
Time of assessment (00:00-23:59)	09:52 (24 HR)
Vital Signs Date and Time (derived)	22 FEB 2021 09:52
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	96 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3552005

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 15:10:29

Generated On: 10 Jun 2021 08:04:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 FEB 2021

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

US3552005

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 16:48:52

Generated On: 10 Jun 2021 08:04:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 FEB 2021
Collection time (00:00-23:59)	10:27 (24 HR)
Collection date and time (derived)	22 FEB 2021 10:27

US3552005

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:06:55

Generated On: 10 Jun 2021 08:04:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552005

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 14:26:04

Generated On: 10 Jun 2021 08:04:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552005

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 14:26:04

Generated On: 10 Jun 2021 08:04:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552005

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552005

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3552005

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:04:59

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

US3552005

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:04:59

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3552005

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

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:20:32

Generated On: 10 Jun 2021 08:04:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3552005

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

Form: Unblinding

Data signed: (b) (4) 23 Mar 2021 15:18:37

Generated On: 10 Jun 2021 08:04:59

Date of updated informed consent (<i>dd MMM yyyy</i>)	27 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	27 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3552005

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 21 Feb 2021 17:20:32

Generated On: 10 Jun 2021 08:04:59

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3552005

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 17:20:32

Generated On: 10 Jun 2021 08:04:59

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 JAN 2021
Time of assessment (00:00-23:59)	08:27 (24 HR)
Vital Signs Date and Time (derived)	27 JAN 2021 08:27
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	101 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

US3552005

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 17:20:32

Generated On: 10 Jun 2021 08:04:59

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 JAN 2021
Time of assessment (00:00-23:59)	09:24 (24 HR)
Vital Signs Date and Time (derived)	27 JAN 2021 09:24
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3552005

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

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 17:20:32

Generated On: 10 Jun 2021 08:04:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 JAN 2021

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

US3552005

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

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 17:20:32

Generated On: 10 Jun 2021 08:04:59

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 27 JAN 2021

What was the treatment time? (00:00-23:59) 08:54 (24 HR)

Treatment Date and Time (derived) 27 JAN 2021 08:54

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

US3552005

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 17:20:32

Generated On: 10 Jun 2021 08:04:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 JAN 2021
Collection time (00:00-23:59)	08:16 (24 HR)
Collection date and time (derived)	27 JAN 2021 08:16

US3552005

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 21 Feb 2021 17:20:32

Generated On: 10 Jun 2021 08:04:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 JAN 2021
Collection time (00:00 - 23:59)	08:18
Collection Date and Time (derived)	27 JAN 2021 08:18

US3552005

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

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:20:32

Generated On: 10 Jun 2021 08:04:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552005

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552005

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:20:33

Generated On: 10 Jun 2021 08:04:59

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3552005

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 03:06:54

Generated On: 10 Jun 2021 08:04:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3552005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Feb 2021 03:06:54

Generated On: 10 Jun 2021 08:04:59

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 FEB 2021
Time of assessment (00:00-23:59)	09:52 (24 HR)
Vital Signs Date and Time (derived)	22 FEB 2021 09:52
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	96 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3552005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Feb 2021 03:06:54

Generated On: 10 Jun 2021 08:04:59

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 FEB 2021
Time of assessment (00:00-23:59)	11:03 (24 HR)
Vital Signs Date and Time (derived)	22 FEB 2021 11:03
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	90 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3552005

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 03:06:54

Generated On: 10 Jun 2021 08:04:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 FEB 2021

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

US3552005

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 26 Feb 2021 03:06:54

Generated On: 10 Jun 2021 08:04:59

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 22 FEB 2021

What was the treatment time? (00:00-23:59) 10:33 (24 HR)

Treatment Date and Time (derived) 22 FEB 2021 10:33

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

US3552005

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:06:54

Generated On: 10 Jun 2021 08:04:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552005

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 16:48:52

Generated On: 10 Jun 2021 08:04:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552005

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 16:48:52

Generated On: 10 Jun 2021 08:04:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552005

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Mar 2021 15:18:37

Generated On: 10 Jun 2021 08:04:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3552005

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Mar 2021 15:18:37

Generated On: 10 Jun 2021 08:04:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 MAR 2021
Time of assessment (00:00-23:59)	14:15 (24 HR)
Vital Signs Date and Time (derived)	22 MAR 2021 14:15
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3552005

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Mar 2021 15:18:37

Generated On: 10 Jun 2021 08:04:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 MAR 2021

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

US3552005

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Mar 2021 15:18:37

Generated On: 10 Jun 2021 08:04:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 MAR 2021
Collection time (00:00-23:59)	14:20 (24 HR)
Collection date and time (derived)	22 MAR 2021 14:20

US3552005

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Mar 2021 15:18:37

Generated On: 10 Jun 2021 08:04:59

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3552005

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

AEID	USA-US089-2021-MRNA-1273-P30 1000004
Adverse event	SEVERE ANEMIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	7 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	12 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	08 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	12 MAR 2021
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

Number of Days in ICU	1
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative	

US3552005

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

SUBJECT ADMITTED TO HOSPITAL FOR RECTAL BLEEDING. MEDICAL RECORD REQUEST SUBMITTED, WILL SEND AS SOON AS WE RECEIVE THEM. UPDATE 3/25/21: SUBJECT PRESENTED TO ED ON 3/8 WITH COMPLAINTS OF WORSENING SOB, FATIGUE, AND LIGHTHEADEDNESS OVER THE PAST WEEK, AS WELL AS BRIGHT RED HEMORRHOIDAL BLEEDING THAT HAD BEEN INTERMITTENT. BLOODWORK WAS DONE, FOUND TO HAVE HEMOGLOBIN OF 3.6; ADMITTED TO ICU FOR SEVERE ANEMIA. RECEIVED 6 UNITS OF BLOOD VIA TRANSFUSION, AS WELL AS UPPER GI ENDOSCOPY AND COLONOSCOPY, WHICH FOUND PROLAPSED, INFLAMED INTERNAL HEMORRHOIDS. ALSO NOTED TO HAVE ACUTE HYPOXIC RESPIRATORY FAILURE DUE TO CONGESTIVE HEART FAILURE EXACERBATION WITH BILATERAL PULMONARY EDEMA ON X-RAY, AS WELL AS ACUTE RENAL FAILURE DUE TO VOLUME DEPLETION. DISCHARGED HOME ON 3L O2 AT NIGHT AND AS NEEDED WITH EXERTION, AS WELL AS MEDICATION CHANGES (SEE CON MEDS). WILL SEND MEDICAL RECORDS.

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)	1

US3552005

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

AEID

Adverse event

INTERNAL HEMORRHOIDS

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)

7 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

12 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

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

US3552005

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

AEID

Adverse event

ACUTE HYPOXIC RESPIRATORY
FAILURE

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)

8 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

12 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
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 (4)

Data signed: (b) (4) 16 Apr 2021 17:57:23

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AEID

Adverse event

ACUTE RENAL FAILURE

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)

8 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

12 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

AEID	
Adverse event	RECTAL PAIN
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	8 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

AEID

Adverse event

EXTERNAL HEMORRHOIDS

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)

7 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

12 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

AEID

Adverse event

SHORTNESS OF BREATH

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)

1 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

12 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 16 Apr 2021 17:57:23

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

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	1 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	12 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 16 Apr 2021 17:57:23

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

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

AEID

Adverse event

LIGHTHEADEDNESS

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)

1 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

12 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 16 Apr 2021 17:57:23

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 21 Feb 2021 17:20:32

Generated On: 10 Jun 2021 08:04:59

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

Name of Medication LIPITOR

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1995
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

Name of Medication BYSTOLIC

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

Name of Medication VASOTEC

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes <input checked="" type="radio"/>	No <input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes <input type="radio"/>	No <input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

Name of Medication SPIRONOLACTONE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 17:57:23

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK	1985
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

Name of Medication LASIX

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2004	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	8 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

Name of Medication ELIQUIS

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2008	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	8 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

Name of Medication TADALAFIL

Prophylaxis Yes ☐
No ☒

Indication PULMONARY HYPERTENSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	8 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

Name of Medication LETAIRIS

Prophylaxis Yes ☐
No ☒

Indication PULMONARY HYPERTENSION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication TYPE 2 DIABETES

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1997	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

Name of Medication VICTOZA

Prophylaxis Yes ☐
No ☒

Indication TYPE 2 DIABETES

Dose per administration 0.6

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1998	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	08 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

Name of Medication	INFLUENZA VACCINE
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	PROPHYLAXIS
Dose per administration	1
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	CC
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		21 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

Name of Medication PNEUMONIA VACCINE

Prophylaxis Yes ☒
No ☐

Indication PNEUMONIA PROPHYLACTIC

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		05 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		05 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

Name of Medication FERROUS SULFATE

Prophylaxis Yes ☒
No ☐

Indication HEALTH

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

Name of Medication LIDOCAINE 5%

Prophylaxis Yes ☐
No ☒

Indication RECTAL PAIN

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication CHRONIC GASTRITIS

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

Name of Medication TAMSULOSIN

Prophylaxis Yes ☐
No ☒

Indication ACUTE RENAL FAILURE

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

Name of Medication ELIQUIS

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

Name of Medication HYDROCODONE/ACETAMINOP
HEN

Prophylaxis Yes ☐
No ☒

Indication RECTAL PAIN, EXCISION OF
INTERNAL AND EXTERNAL
HEMORRHOIDS

Dose per administration 5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐
No ☒

Indication ACUTE HYPOXIC RESPIRATORY
FAILURE

Dose per administration 60

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication TYPE II DIABETES

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

Name of Medication TADALAFIL

Prophylaxis Yes ☐
No ☒

Indication PULMONARY HYPERTENSION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

Name of Medication BLOOD [PACKED RED BLOOD CELLS]

Prophylaxis Yes ☐
No ☒

Indication SEVERE ANEMIA,
LIGHTHEADEDNESS,
SHORTNESS OF BREATH,
FATIGUE

Dose per administration 6

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

If dose unit is Other, specify UNITS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	8 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	12 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

Name of Medication VICTOZA

Prophylaxis Yes ☐
No ☒

Indication TYPE 2 DIABETES

Dose per administration 1.8

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 16 Apr 2021 17:57:23

Generated On: 10 Jun 2021 08:04:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3552005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 14:26:04

Generated On: 10 Jun 2021 08:04:59

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3552005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 29 Mar 2021 13:55:28

Generated On: 10 Jun 2021 08:04:59

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
7 MAR 2021	UPPER GI ENDOSCOPY	Adverse Event	
7 MAR 2021	COLONOSCOPY	Adverse Event	
7 MAR 2021	EXCISION OF INTERNAL AND EXTERNAL HEMORRHOIDS	Adverse Event	

US3552005

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:04:59

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

US3552005

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:04:59

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 ☐

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 16 Apr 2021 17:57:24

Generated On: 10 Jun 2021 08:04:59

SAEID	USA-US089-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Apr 2021 17:57:24

Generated On: 10 Jun 2021 08:04:59

SAEID	USA-US089-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5
Date of submission (Pre-filled from custom function)	23/MAR/2021 10:08
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

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 16 Apr 2021 17:57:24

Generated On: 10 Jun 2021 08:04:59

SAEID	USA-US089-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5
Date of submission (Pre-filled from custom function)	26/MAR/2021 09:19
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

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 16 Apr 2021 17:57:24

Generated On: 10 Jun 2021 08:04:59

SAEID	USA-US089-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5
Date of submission (Pre-filled from custom function)	01/APR/2021 09:05
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

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 16 Apr 2021 17:57:24

Generated On: 10 Jun 2021 08:04:59

SAEID	USA-US089-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5
Date of submission (Pre-filled from custom function)	06/APR/2021 09:47
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

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form (5)

Data signed: (b) (4) 16 Apr 2021 17:57:24

Generated On: 10 Jun 2021 08:04:59

SAEID	USA-US089-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5
Date of submission (Pre-filled from custom function)	09/APR/2021 06:08
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

Audit

US3552005 (Prod: Saint Louis University)

US3552005

Form: Participant Creation

Generated On: 10 Jun 2021 08:04:59

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:18:51
User entered 'US3552005'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 16:04:45

US3552005

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:04:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 20:57:32

US3552005

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '11 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 16:04:46

US3552005

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Clinic (Clinic)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 20:57:32

US3552005

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:04:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered 'SCRN'	System	11 Aug 2020 20:57:32

US3552005

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:04:59

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered (b) (6) 1955'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 16:04:47

US3552005

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:04:59

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '65'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 20:58:33

US3552005

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:04:59

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered 'YEARS'	System	11 Aug 2020 20:58:33

US3552005

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:04:59

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered '65'	System	11 Aug 2020 16:06:42

US3552005

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:04:59

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Male (M)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 20:58:33

US3552005

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:04:59

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Mikayla Frye (b) (4)	11 Aug 2020 20:58:33

US3552005

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:04:59

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'l'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 20:58:33

US3552005

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:04:59

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'l'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 20:58:33

US3552005

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:04:59

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 20:58:33

US3552005

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:04:59

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'I'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 20:58:33

US3552005

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:04:59

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 20:58:33

US3552005

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:04:59

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 20:58:33

US3552005

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:04:59

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 20:58:33

US3552005

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:04:59

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 20:58:33

US3552005

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:04:59

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 20:58:33

US3552005

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:04:59

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '11 Aug 2020'	(b) (4) Janice Tennant (b) (4)	11 Aug 2020 16:06:42

US3552005

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered 'Aug 2020'	System	11 Aug 2020 16:06:42

US3552005

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered '2020'	System	11 Aug 2020 16:06:42

US3552005

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:04:59

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Amendment 2 (2)'	(b) (4) Janice Tennant (b) (4)	11 Aug 2020 16:06:42

US3552005

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Janice Tennant (b) (4)	11 Aug 2020 16:06:42

US3552005

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Janice Tennant (b) (4)	11 Aug 2020 16:06:42

US3552005

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:04:59

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Janice Tennant (b) (4)	11 Aug 2020 16:06:42

US3552005

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:04:59

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Janice Tennant (b) (4)	11 Aug 2020 16:06:42

US3552005

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:04:59

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 16:04:46

US3552005

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:04:59

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered 'l'	System	11 Aug 2020 16:06:52

US3552005

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Janice Tennant (b) (4)	11 Aug 2020 16:06:52

US3552005

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:04:59

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:00:23

US3552005

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:04:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	11 Aug 2020 21:06:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 21:06:14
Data point term sent to Coder	System	11 Aug 2020 21:05:28
User entered 'Hypercholesterolemia'	Mikayla Frye (b) (4)	11 Aug 2020 21:04:47
	(b) (4)	

US3552005

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'UN UNK 1995'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:04:47

US3552005

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:04:47

US3552005

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:04:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:04:47

US3552005

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:04:47

US3552005

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:04:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:04:47

US3552005

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered 'Jan 1995'	System	11 Aug 2020 21:04:47

US3552005

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered '1995'	System	11 Aug 2020 21:04:47

US3552005

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered empty.	System	11 Aug 2020 21:04:47

US3552005

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered empty.	System	11 Aug 2020 21:04:47

US3552005

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:04:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	11 Aug 2020 21:07:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 21:07:17
Data point term sent to Coder	System	11 Aug 2020 21:06:29
User entered 'Hypertension'	Mikayla Frye (b) (4)	11 Aug 2020 21:05:30
	(b) (4)	

US3552005

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'UN UNK 1985'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:05:30

US3552005

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:05:30

US3552005

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:04:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:05:30

US3552005

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:05:30

US3552005

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:04:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:05:30

US3552005

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered 'Jan 1985'	System	11 Aug 2020 21:05:30

US3552005

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered '1985'	System	11 Aug 2020 21:05:30

US3552005

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered empty.	System	11 Aug 2020 21:05:30

US3552005

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered empty.	System	11 Aug 2020 21:05:30

US3552005

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:04:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	11 Aug 2020 21:08:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 21:08:18
Data point term sent to Coder	System	11 Aug 2020 21:07:30
User entered 'Atrial fibrillation'	Mikayla Frye (b) (4)	11 Aug 2020 21:06:53
	(b) (4)	

US3552005

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'UN UNK 2008'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:06:53

US3552005

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:06:53

US3552005

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:04:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:06:53

US3552005

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:06:53

US3552005

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:04:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:06:53

US3552005

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered 'Jan 2008'	System	11 Aug 2020 21:06:53

US3552005

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:04:59

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered '2008'	System	11 Aug 2020 21:06:53

US3552005

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered empty.	System	11 Aug 2020 21:06:53

US3552005

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered empty.	System	11 Aug 2020 21:06:53

US3552005

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:04:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Pulmonary vascular disorders, HLT: Pulmonary hypertension, PT: Pulmonary hypertension, LLT: Pulmonary hypertension - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 21:09:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 21:09:20
Data point term sent to Coder	System	11 Aug 2020 21:08:31
User entered 'Pulmonary Hypertension'	Mikayla Frye (b) (4)	11 Aug 2020 21:07:56

US3552005

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'UN UNK 2009'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:07:56

US3552005

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:07:56

US3552005

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:04:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:07:56

US3552005

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:07:56

US3552005

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:04:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:07:56

US3552005

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered 'Jan 2009'	System	11 Aug 2020 21:07:56

US3552005

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered '2009'	System	11 Aug 2020 21:07:56

US3552005

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered empty.	System	11 Aug 2020 21:07:56

US3552005

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered empty.	System	11 Aug 2020 21:07:56

US3552005

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:04:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary artery bypass, LLT: Quadruple vessel bypass graft - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 13:01:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 13:01:17
Data point term sent to Coder	System	12 Aug 2020 13:29:59
User entered 'quadruple bypass' reason for change:	Joan Siegner (b) (4)	12 Aug 2020 13:29:19
Data Entry Error		
Data point term sent to Coder	System	11 Aug 2020 21:09:32
User entered 'Quadruple Bypass Heart Surgery'	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:08:37

US3552005

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Un UNK 2002'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:08:37

US3552005

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:08:37

US3552005

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:04:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:08:37

US3552005

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'UN UNK 2002'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:08:37

US3552005

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:04:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:08:37

US3552005

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered 'Jan 2002'	System	11 Aug 2020 21:08:37

US3552005

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered '2002'	System	11 Aug 2020 21:08:37

US3552005

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered 'Jan 2002'	System	11 Aug 2020 21:08:37

US3552005

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered '2002'	System	11 Aug 2020 21:08:37

US3552005

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:04:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
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)	11 Aug 2020 21:11:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 21:11:22
Data point term sent to Coder	System	11 Aug 2020 21:09:34
User entered 'Type 2 Diabetes'	Mikayla Frye (b) (4)	11 Aug 2020 21:09:07

US3552005

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Un UNK 1997'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:09:07

US3552005

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:09:07

US3552005

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:04:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:09:07

US3552005

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:09:07

US3552005

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:04:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:09:07

US3552005

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered 'Jan 1997'	System	11 Aug 2020 21:09:07

US3552005

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:04:59

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered '1997'	System	11 Aug 2020 21:09:07

US3552005

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered empty.	System	11 Aug 2020 21:09:07

US3552005

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered empty.	System	11 Aug 2020 21:09:07

US3552005

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:04:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 06:51:34
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 19:40:19
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 14:11:13
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 21:11:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 21:11:23
Data point term sent to Coder	System	11 Aug 2020 21:10:35
User entered 'Cholecystectomy'	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:09:52

US3552005

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'UN UNK 2016'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:09:52

US3552005

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:09:52

US3552005

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:04:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:09:52

US3552005

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'UN UNK 2016'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:09:52

US3552005

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:04:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:09:52

US3552005

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered 'Jan 2016'	System	11 Aug 2020 21:09:52

US3552005

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered '2016'	System	11 Aug 2020 21:09:52

US3552005

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered 'Jan 2016'	System	11 Aug 2020 21:09:52

US3552005

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered '2016'	System	11 Aug 2020 21:09:52

US3552005

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:04:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Testicular and epididymal disorders, HLT: Testicular and epididymal neoplasms, PT: Testicular cyst, LLT: Testicular cyst - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:07:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:07:11
Data point term sent to Coder	System	11 Aug 2020 21:11:36
User entered 'Benign Cyst Testicular'	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:10:54

US3552005

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'UN UNK 1973'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:10:54

US3552005

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:10:54

US3552005

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:04:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:10:54

US3552005

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'UN UNK 1973'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:10:54

US3552005

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:04:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:10:54

US3552005

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered 'Jan 1973'	System	11 Aug 2020 21:10:54

US3552005

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered '1973'	System	11 Aug 2020 21:10:54

US3552005

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered 'Jan 1973'	System	11 Aug 2020 21:10:54

US3552005

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered '1973'	System	11 Aug 2020 21:10:54

US3552005

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:04:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin lesion excisions, PT: Skin cyst excision, LLT: Skin cyst excision - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:28:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:28:54
Data point term sent to Coder	System	11 Aug 2020 21:13:41
User entered 'Left Neck Benign Cyst Removal'	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:13:33

US3552005

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'UN UNK 1985'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:13:33

US3552005

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:13:33

US3552005

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:04:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:13:33

US3552005

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'UN UNK 1985'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:13:33

US3552005

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:04:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:13:33

US3552005

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered 'Jan 1985'	System	11 Aug 2020 21:13:33

US3552005

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:04:59

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered '1985'	System	11 Aug 2020 21:13:33

US3552005

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered 'Jan 1985'	System	11 Aug 2020 21:13:33

US3552005

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered '1985'	System	11 Aug 2020 21:13:33

US3552005

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:04:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
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: Lumbar disc herniation - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 12:02:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 12:02:15
Data point term sent to Coder	System	11 Aug 2020 21:14:41
User entered 'L5 Disk Herniation'	Mikayla Frye (b) (4)	11 Aug 2020 21:14:06

US3552005

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'UN UNK 1982'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:14:06

US3552005

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:14:06

US3552005

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:04:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:14:06

US3552005

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'UN UNK 1982'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:14:06

US3552005

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:04:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:14:06

US3552005

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered 'Jan 1982'	System	11 Aug 2020 21:14:06

US3552005

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:04:59

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered '1982'	System	11 Aug 2020 21:14:06

US3552005

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered 'Jan 1982'	System	11 Aug 2020 21:14:06

US3552005

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered '1982'	System	11 Aug 2020 21:14:06

US3552005

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:04:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
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 degeneration, LLT: Cervical disc degeneration - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	13 Aug 2020 07:49:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 07:49:19
Data point term sent to Coder	System	11 Aug 2020 21:16:42
User entered 'C-3 Degenerative Disk Disease'	Mikayla Frye (b) (4)	11 Aug 2020 21:16:29

US3552005

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'UN UNK 2000'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:16:29

US3552005

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:16:29

US3552005

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:04:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:16:29

US3552005

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:16:29

US3552005

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:04:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:16:29

US3552005

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered 'Jan 2000'	System	11 Aug 2020 21:16:29

US3552005

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered '2000'	System	11 Aug 2020 21:16:29

US3552005

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered empty.	System	11 Aug 2020 21:16:29

US3552005

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered empty.	System	11 Aug 2020 21:16:29

US3552005

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:04:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
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 degeneration, LLT: Intervertebral disc degeneration - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 21:04:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 21:04:43
Data point term sent to Coder	System	11 Aug 2020 21:17:45
User entered 'T-3 Degenerative Disk Disease'	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:16:52

US3552005

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'UN UNK 2000'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:16:52

US3552005

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:16:52

US3552005

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:04:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:16:52

US3552005

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:16:52

US3552005

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:04:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:16:52

US3552005

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered 'Jan 2000'	System	11 Aug 2020 21:16:52

US3552005

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:04:59

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered '2000'	System	11 Aug 2020 21:16:52

US3552005

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered empty.	System	11 Aug 2020 21:16:52

US3552005

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered empty.	System	11 Aug 2020 21:16:52

US3552005

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:04:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
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.	(b) (4) Coder Import (b) (4)	11 Aug 2020 21:19:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 21:19:12
Data point term sent to Coder	System	11 Aug 2020 21:17:45
User entered 'Seasonal Allergies'	Mikayla Frye (b) (4)	11 Aug 2020 21:17:17
	(b) (4)	

US3552005

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'UN UNK 1965'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:17:17

US3552005

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:17:17

US3552005

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:04:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:17:17

US3552005

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:17:17

US3552005

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:04:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:17:17

US3552005

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered 'Jan 1965'	System	11 Aug 2020 21:17:17

US3552005

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:04:59

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered '1965'	System	11 Aug 2020 21:17:17

US3552005

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered empty.	System	11 Aug 2020 21:17:17

US3552005

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered empty.	System	11 Aug 2020 21:17:17

US3552005

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:04:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Cholelithiasis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 19:45:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 19:45:00
Data point term sent to Coder	System	01 Oct 2020 19:43:38
User entered 'cholelithiasis'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 19:43:30

US3552005

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 19:43:30

US3552005

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 19:43:30

US3552005

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:04:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 19:43:30

US3552005

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'un UNK 2016'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 19:43:30

US3552005

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:04:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 19:43:30

US3552005

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered empty.	System	01 Oct 2020 19:43:30

US3552005

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:04:59

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered empty.	System	01 Oct 2020 19:43:30

US3552005

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered 'Jan 2016'	System	01 Oct 2020 19:43:30

US3552005

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered '2016'	System	01 Oct 2020 19:43:30

US3552005

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:04:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Gastritis (excl infective), PT: Chronic gastritis, LLT: Chronic gastritis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	25 Mar 2021 17:16:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 17:16:29
Data point term sent to Coder	System	25 Mar 2021 17:15:37
User entered 'chronic gastritis'	Heather Douds (b) (4)	25 Mar 2021 17:15:35
	(b) (4)	

US3552005

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	29 Mar 2021 13:55:30
User entered empty.	Heather Douds (b) (4) (b) (4)	25 Mar 2021 17:15:35

US3552005

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'l'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 17:15:35

US3552005

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:04:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 17:15:35

US3552005

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	29 Mar 2021 13:55:30
User entered empty.	Heather Douds (b) (4) (b) (4)	25 Mar 2021 17:15:35

US3552005

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:04:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 17:15:35

US3552005

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered empty.	System	25 Mar 2021 17:15:35

US3552005

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered empty.	System	25 Mar 2021 17:15:35

US3552005

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered empty.	System	25 Mar 2021 17:15:35

US3552005

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered empty.	System	25 Mar 2021 17:15:35

US3552005

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:04:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User coded data point as SOC: Cardiac disorders, HLGT: Myocardial disorders, HLT: Cardiomyopathies, PT: Ischaemic cardiomyopathy, LLT: Ischemic cardiomyopathy - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 18:39:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 18:39:29
Data point term sent to Coder System	System	25 Mar 2021 18:22:50
User entered 'ischemic cardiomyopathy'	Heather Douds (b) (4)	25 Mar 2021 18:22:32

US3552005

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	29 Mar 2021 13:55:30
User entered empty.	Heather Douds (b) (4) (b) (4)	25 Mar 2021 18:22:32

US3552005

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'l'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 18:22:32

US3552005

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:04:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	29 Mar 2021 13:55:30
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	25 Mar 2021 18:22:32

US3552005

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	29 Mar 2021 13:55:30
User entered empty.	Heather Douds (b) (4) (b) (4)	25 Mar 2021 18:22:32

US3552005

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:04:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 18:22:32

US3552005

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered empty.	System	25 Mar 2021 18:22:32

US3552005

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered empty.	System	25 Mar 2021 18:22:32

US3552005

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered empty.	System	25 Mar 2021 18:22:32

US3552005

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered empty.	System	25 Mar 2021 18:22:32

US3552005

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:19:26

US3552005

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '11 Aug 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:19:26

US3552005

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '10:00'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:19:26

US3552005

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered '11 Aug 2020 10:00'	System	11 Aug 2020 21:19:26

US3552005

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '68.5' in	(b) (4) Mikayla Frye (b) (4)	11 Aug 2020 21:19:26
DataPoint set to visible.	(b) (4) System	11 Aug 2020 16:06:52

US3552005

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '218' lb	(b) (4) Mikayla Frye (b) (4)	11 Aug 2020 21:19:26
DataPoint set to visible.	(b) (4) System	11 Aug 2020 16:06:52

US3552005

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
Amendment Manager: User entered '32.73296'	System	16 Sep 2020 23:51:44
User entered '32.7'	System	11 Aug 2020 21:19:26
DataPoint set to visible.	System	11 Aug 2020 16:06:52

US3552005

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered 'kg/m2'	System	11 Aug 2020 21:19:26
DataPoint set to visible.	System	11 Aug 2020 16:06:52

US3552005

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 02:33:32
User entered missing code ND - Not Done; reason for change Data Entry Error	Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 18:32:55
Query 'Data is required. Please provide.' answered with 'See pre- and post-dosing on randomization visit.' (Site from System).	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:20:00
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 21:19:26
User entered empty.	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:19:26

US3552005

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 02:33:34
Query 'Data is required. Please provide.' answered with 'See pre- and post-dosing on randomization visit.' (Site from System).	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:20:07
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 21:19:26
User entered empty.	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:19:26

US3552005

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:19:26

US3552005

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 02:33:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 18:32:55
Query 'Data is required. Please provide.' answered with 'See pre- and post-dosing on randomization visit.' (Site from System).	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:20:13
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 21:19:26
User entered empty.	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:19:26

US3552005

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered 'bpm'	System	12 Aug 2020 18:32:55
User entered empty.	System	11 Aug 2020 21:19:26

US3552005

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 02:33:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 18:32:55
Query 'Data is required. Please provide.' answered with 'See pre- and post-dosing on randomization visit.' (Site from System).	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:20:17
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 21:19:26
User entered empty.	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:19:26

US3552005

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered 'breaths/min'	System	12 Aug 2020 18:32:55
User entered empty.	System	11 Aug 2020 21:19:26

US3552005

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 02:33:40
User entered missing code ND - Not Done; reason for change Data Entry Error	Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 18:32:55
Query 'Data is required. Please provide.' answered with 'See pre- and post-dosing on randomization visit.' (Site from System).	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:20:21
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 21:19:26
User entered empty.	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:19:26

US3552005

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered 'mmHg'	System	12 Aug 2020 18:32:55
User entered empty.	System	11 Aug 2020 21:19:26

US3552005

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 02:33:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 18:32:55
Query 'Data is required. Please provide.' answered with 'See pre- and post-dosing on randomization visit.' (Site from System).	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:20:25
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 21:19:26
User entered empty.	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:19:26

US3552005

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User entered 'mmHg'	System	12 Aug 2020 18:32:55
User entered empty.	System	11 Aug 2020 21:19:26

US3552005

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47

US3552005

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47

US3552005

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:04:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:21:36

US3552005

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:04:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	08 Sep 2020 10:23:36
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	07 Sep 2020 13:54:46
User entered '11 Aug 2020'	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:21:36

US3552005

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:27:24

US3552005

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:27:24

US3552005

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:27:24

US3552005

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:27:24

US3552005

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:27:24

US3552005

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:27:24

US3552005

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:27:24

US3552005

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:27:24

US3552005

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:27:24

US3552005

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:27:24

US3552005

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:27:24

US3552005

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:59

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:27:24

US3552005

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:59

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'Church services 1x per week.'	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:27:24

US3552005

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:59

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:27:24

US3552005

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:27:24

US3552005

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:27:24

US3552005

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:27:24

US3552005

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:27:24

US3552005

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'l'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:27:24

US3552005

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:59

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:27:24

US3552005

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:04:59

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:27:24

US3552005

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:04:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:29:40

US3552005

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '11 Aug 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:29:40

US3552005

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Clinic (Clinic)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:29:40

US3552005

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:04:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered 'VISIT1'	System	11 Aug 2020 21:29:40

US3552005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '11 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 16:05:04

US3552005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 03:34:59
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:34:58
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 16:05:04
User entered '185651' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 16:05:04

US3552005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 16:05:04

US3552005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:30:53

US3552005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:30:53

US3552005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:30:53

US3552005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:04:59

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Joan Siegner (b) (4)	14 Sep 2020 18:30:05
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:30:53

US3552005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:04:59

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:30:53

US3552005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4)	21 Sep 2020 16:53:59
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 10:17:35
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:31:07

US3552005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:04:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Aug 2020 16:31:41
User entered empty.	Stanley Dublin (b) (4)	13 Aug 2020 16:31:41
	(b) (4)	
	Mikayla Frye (b) (4)	11 Aug 2020 21:33:27
	(b) (4)	

US3552005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:04:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Aug 2020 16:31:41
User entered empty.	Stanley Dublin (b) (4)	13 Aug 2020 16:31:41
	(b) (4)	
	Mikayla Frye (b) (4)	11 Aug 2020 21:33:27
	(b) (4)	

US3552005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:04:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Aug 2020 16:31:41
User entered empty.	Stanley Doublin (b) (4)	13 Aug 2020 16:31:41
	(b) (4)	
	Mikayla Frye (b) (4)	11 Aug 2020 21:33:27
	(b) (4)	

US3552005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:04:59

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Aug 2020 16:31:41
User entered empty.	Stanley Dublin (b) (4)	13 Aug 2020 16:31:41
	(b) (4)	
	Mikayla Frye (b) (4)	11 Aug 2020 21:33:27
	(b) (4)	

US3552005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User accepted default value 'Pre-Dose (PREDOSE)'	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:33:27

US3552005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:33:27

US3552005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '11 Aug 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:33:27

US3552005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '10:00'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:33:27

US3552005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered '11 Aug 2020 10:00'	System	11 Aug 2020 21:33:27

US3552005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '98.5' F	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:33:27

US3552005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Oral (Oral)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:33:27

US3552005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:33:27

US3552005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '68'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:33:27

US3552005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered 'bpm'	System	11 Aug 2020 21:33:27

US3552005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '16'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:33:27

US3552005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered 'breaths/min'	System	11 Aug 2020 21:33:27

US3552005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '134'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:33:27

US3552005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered 'mmHg'	System	11 Aug 2020 21:33:27

US3552005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '81'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:33:27

US3552005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered 'mmHg'	System	11 Aug 2020 21:33:27

US3552005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:04:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Aug 2020 16:31:41
User entered empty.	Stanley Dublin (b) (4)	13 Aug 2020 16:31:41
	(b) (4)	
	Mikayla Frye (b) (4)	11 Aug 2020 21:33:27
	(b) (4)	

US3552005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:04:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Aug 2020 16:31:41
User entered empty.	Stanley Dublin (b) (4)	13 Aug 2020 16:31:41
	(b) (4)	
	Mikayla Frye (b) (4)	11 Aug 2020 21:33:27
	(b) (4)	

US3552005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User accepted default value 'Post-Dose (POSTDOSE)'	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:33:27

US3552005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:33:27

US3552005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '11 Aug 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:33:27

US3552005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 09:59:52
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Time is correct.' (Site from System).	Mikayla Frye (b) (4)	11 Aug 2020 21:33:43
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		11 Aug 2020 21:33:27
User entered '12:10'	Mikayla Frye (b) (4)	11 Aug 2020 21:33:27

US3552005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered '11 Aug 2020 12:10'	System	11 Aug 2020 21:33:27

US3552005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '98.4' F	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:33:27

US3552005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'Oral (Oral)'	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:33:27

US3552005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered empty.	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:33:27

US3552005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered '69'	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:33:27

US3552005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered 'bpm'	System	11 Aug 2020 21:33:27

US3552005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered '16'	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:33:27

US3552005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered 'breaths/min'	System	11 Aug 2020 21:33:27

US3552005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered '118'	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:33:27

US3552005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered 'mmHg'	System	11 Aug 2020 21:33:27

US3552005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered '68'	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:33:27

US3552005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered 'mmHg'	System	11 Aug 2020 21:33:27

US3552005

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:04:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:34:04

US3552005

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:04:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered empty.	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:34:04

US3552005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	Janice Tennant (b) (4)	11 Aug 2020 16:46:41

US3552005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered empty.	Janice Tennant (b) (4) (b) (4)	11 Aug 2020 16:46:41

US3552005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered empty.	Janice Tennant (b) (4) [REDACTED]	11 Aug 2020 16:46:41

US3552005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered 'MRNA-1273 OR PLACEBO'	System	11 Aug 2020 16:46:41

US3552005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '11 Aug 2020'	(b) (4) Janice Tennant (b) (4)	11 Aug 2020 16:46:41

US3552005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered '11:40'	Janice Tennant (b) (4) (b) (4)	11 Aug 2020 16:46:41

US3552005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered '11 Aug 2020 11:40'	System	11 Aug 2020 16:46:41

US3552005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Left Arm (LEFT ARM)'	(b) (4) Janice Tennant (b) (4)	11 Aug 2020 16:46:41

US3552005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered 'ONCE'	System	11 Aug 2020 16:46:41

US3552005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered 'INTRAMUSCULAR'	System	11 Aug 2020 16:46:41

US3552005

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:35:09

US3552005

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '11 Aug 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:35:09

US3552005

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered '10:49'	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:35:09

US3552005

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered '11 Aug 2020 10:49'	System	11 Aug 2020 21:35:09

US3552005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:04:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered '11 Aug 2020'	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:35:32

US3552005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:04:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:35:32

US3552005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:04:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:35:32

US3552005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:04:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered '10:50'	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:35:32

US3552005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:04:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered '11 Aug 2020 10:50'	System	11 Aug 2020 21:35:32

US3552005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:04:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:35:32

US3552005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:04:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:35:32

US3552005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:04:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:35:32

US3552005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:04:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered empty.	System	11 Aug 2020 21:35:32

US3552005

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	25 Aug 2020 15:20:57

US3552005

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered 'l'	System	25 Aug 2020 15:20:57

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-11T12:12:20', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '6542782f-59ee-4f87-bde1-446dfd2534eb'	System	11 Aug 2020 17:12:48
User entered 'Yes (Y)'	System	11 Aug 2020 17:12:48

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-11T12:12:32', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '6542782f-59ee-4f87-bde1-446dfd2534eb'	System	11 Aug 2020 17:12:48
User entered '98.4'	System	11 Aug 2020 17:12:48

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-11T12:12:38', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '6542782f-59ee-4f87-bde1-446dfd2534eb'	System	11 Aug 2020 17:12:48
User entered 'No (N)'	System	11 Aug 2020 17:12:48

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-11T12:12:47', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '6542782f-59ee-4f87-bde1-446dfd2534eb'	System	11 Aug 2020 17:12:48
User entered '11 Aug 2020 12:12'	System	11 Aug 2020 17:12:48

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '11 Aug 2020 12:00'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '11 Aug 2020 14:30'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-11T16:13:33', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '74e8b784-f0ab-4ea1-8dbe-c1736c90f5e1'	System	11 Aug 2020 21:13:59
User entered 'Yes (Y)'	System	11 Aug 2020 21:13:59

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-11T16:13:41', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '74e8b784-f0ab-4ea1-8dbe-e1736c90f5e1'	System	11 Aug 2020 21:13:59
User entered '98.7'	System	11 Aug 2020 21:13:59

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-11T16:13:52', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '74e8b784-f0ab-4ea1-8dbe-e1736c90f5e1'	System	11 Aug 2020 21:13:59
User entered 'No (N)'	System	11 Aug 2020 21:13:59

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-11T16:13:57', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '74e8b784-f0ab-4ea1-8dbe-e1736c90f5e1'	System	11 Aug 2020 21:13:59
User entered '11 Aug 2020 16:13'	System	11 Aug 2020 21:13:59

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '11 Aug 2020 15:25'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered 'Day 2'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:04:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-12T12:02:02', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'f3529f00-4b5b-4621-99b7-3b9043280ab6'	System	12 Aug 2020 17:02:27
User entered 'Yes (Y)'	System	12 Aug 2020 17:02:27

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:04:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-12T12:02:10', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'f3529f00-4b5b-4621-99b7-3b9043280ab6' User entered '98.1'	System	12 Aug 2020 17:02:27
	System	12 Aug 2020 17:02:27

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-12T12:02:15', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'f3529f00-4b5b-4621-99b7-3b9043280ab6'	System	12 Aug 2020 17:02:27
User entered 'No (N)'	System	12 Aug 2020 17:02:27

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-12T12:02:19', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'f3529f00-4b5b-4621-99b7-3b9043280ab6'	System	12 Aug 2020 17:02:27
User entered '12 Aug 2020 12:02'	System	12 Aug 2020 17:02:27

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered 'Day 3'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:04:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-13T12:46:32', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '64edc989-b1bf-4d9e-8d6e-0f022cc3328e'	System	13 Aug 2020 17:46:55
User entered 'Yes (Y)'	System	13 Aug 2020 17:46:55

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:04:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-13T12:46:39', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '64edc989-b1bf-4d9e-8d6e-0f022cc3328e' User entered '98.4'	System	13 Aug 2020 17:46:55
	System	13 Aug 2020 17:46:55

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-13T12:46:46', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '64edc989-b1bf-4d9e-8d6e-0f022cc3328e'	System	13 Aug 2020 17:46:55
User entered 'No (N)'	System	13 Aug 2020 17:46:55

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-13T12:46:50', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '64edc989-b1bf-4d9e-8d6e-0f022cc3328e'	System	13 Aug 2020 17:46:55
User entered '13 Aug 2020 12:46'	System	13 Aug 2020 17:46:55

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered 'Day 4'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:04:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-14T12:09:48', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '302f23a4-bf2c-4caf-a347-181b81907c3b'	System	14 Aug 2020 17:10:12
User entered 'Yes (Y)'	System	14 Aug 2020 17:10:12

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:04:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-14T12:09:55', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '302f23a4-bf2c-4caf-a347-181b81907c3b'	System	14 Aug 2020 17:10:12
User entered '98.2'	System	14 Aug 2020 17:10:12

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-14T12:10:01', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '302f23a4-bf2c-4caf-a347-181b81907c3b'	System	14 Aug 2020 17:10:12
User entered 'No (N)'	System	14 Aug 2020 17:10:12

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-14T12:10:07', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '302f23a4-bf2c-4caf-a347-181b81907c3b'	System	14 Aug 2020 17:10:12
User entered '14 Aug 2020 12:10'	System	14 Aug 2020 17:10:12

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered 'Day 5'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:04:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-15T12:51:43', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '6c13890d-1ea1-456d-a8b8-591f71f2817c'	System	15 Aug 2020 17:52:00
User entered 'Yes (Y)'	System	15 Aug 2020 17:52:00

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:04:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-15T12:51:50', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '6c13890d-1ea1-456d-a8b8-591f71f2817c'	System	15 Aug 2020 17:52:00
User entered '98.2'	System	15 Aug 2020 17:52:00

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-15T12:51:54', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '6c13890d-1ea1-456d-a8b8-591f71f2817c'	System	15 Aug 2020 17:52:00
User entered 'No (N)'	System	15 Aug 2020 17:52:00

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-15T12:51:57', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '6c13890d-1ea1-456d-a8b8-591f71f2817c'	System	15 Aug 2020 17:52:00
User entered '15 Aug 2020 12:51'	System	15 Aug 2020 17:52:00

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered 'Day 6'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:04:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-16T12:24:53', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '44cb92ce-a184-4add-8f13-ccd3f6f5a2f2'	System	16 Aug 2020 17:25:15
User entered 'Yes (Y)'	System	16 Aug 2020 17:25:15

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:04:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-16T12:25:02', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '44cb92ce-a184-4add-8f13-ccd3f6f5a2f2'	System	16 Aug 2020 17:25:15
User entered '98.5'	System	16 Aug 2020 17:25:15

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-16T12:25:07', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '44cb92ce-a184-4add-8f13-ecd3f6f5a2f2'	System	16 Aug 2020 17:25:15
User entered 'No (N)'	System	16 Aug 2020 17:25:15

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-16T12:25:13', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '44cb92ce-a184-4add-8f13-ccd3f6f5a2f2'	System	16 Aug 2020 17:25:15
User entered '16 Aug 2020 12:25'	System	16 Aug 2020 17:25:15

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered 'Day 7'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:04:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-17T12:03:09', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '5ddf110c-a54a-4940-9436-466f70b0f5e4'	System	17 Aug 2020 17:03:54
User entered 'Yes (Y)'	System	17 Aug 2020 17:03:54

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:04:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-17T12:03:34', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '5ddf110c-a54a-4940-9436-466f70b0f5e4' User entered '97.6'	System	17 Aug 2020 17:03:54
	System	17 Aug 2020 17:03:54

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-17T12:03:40', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '5ddf110c-a54a-4940-9436-466f70b0f5e4'	System	17 Aug 2020 17:03:54
User entered 'No (N)'	System	17 Aug 2020 17:03:54

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-17T12:03:47', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '5ddfl10c-a54a-4940-9436-466f70b0f5e4'	System	17 Aug 2020 17:03:54
User entered '17 Aug 2020 12:03'	System	17 Aug 2020 17:03:54

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-11T12:13:02', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '6fa6ed8a-39b1-4c09-8a9c-195abc747048'	System	11 Aug 2020 17:13:49
User entered 'None (1)'	System	11 Aug 2020 17:13:49

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-11T12:13:07', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '6fa6ed8a-39b1-4c09-8a9c-195abc747048'	System	11 Aug 2020 17:13:49
User entered 'No (N)'	System	11 Aug 2020 17:13:49

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-11T12:13:11', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '6fa6ed8a-39b1-4c09-8a9c-195abc747048'	System	11 Aug 2020 17:13:49
User entered 'No (N)'	System	11 Aug 2020 17:13:49

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-11T12:13:38', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '6fa6ed8a-39b1-4c09-8a9c-195abc747048'	System	11 Aug 2020 17:13:49
User entered 'None (1)'	System	11 Aug 2020 17:13:49

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-11T12:13:46', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '6fa6ed8a-39b1-4c09-8a9c-195abc747048'	System	11 Aug 2020 17:13:49
User entered '11 Aug 2020 12:13'	System	11 Aug 2020 17:13:49

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '11 Aug 2020 12:00'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '11 Aug 2020 14:30'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-11T16:14:07', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '972197e5-77eb-4abe-8482-92213ef5e058'	System	11 Aug 2020 21:14:56
User entered 'None (1)'	System	11 Aug 2020 21:14:56

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-11T16:14:28', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '972197e5-77eb-4abe-8482-92213ef5e058'	System	11 Aug 2020 21:14:56
User entered 'No (N)'	System	11 Aug 2020 21:14:56

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-11T16:14:36', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '972197e5-77eb-4abe-8482-92213ef5e058'	System	11 Aug 2020 21:14:56
User entered 'No (N)'	System	11 Aug 2020 21:14:56

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-11T16:14:49', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '972197e5-77eb-4abe-8482-92213ef5e058'	System	11 Aug 2020 21:14:56
User entered 'None (1)'	System	11 Aug 2020 21:14:56

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-11T16:14:53', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '972197e5-77eb-4abe-8482-92213ef5e058'	System	11 Aug 2020 21:14:56
User entered '11 Aug 2020 16:14'	System	11 Aug 2020 21:14:56

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '11 Aug 2020 15:25'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered 'Day 2'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:04:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-12T12:02:26', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '0728c952-02de-4247-aa8e-7444e148a29d'	System	12 Aug 2020 17:02:43
User entered 'None (1)'	System	12 Aug 2020 17:02:43

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:04:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-12T12:02:29', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '0728c952-02de-4247-aa8e-7444e148a29d'	System	12 Aug 2020 17:02:43
User entered 'No (N)'	System	12 Aug 2020 17:02:43

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-12T12:02:33', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '0728c952-02de-4247-aa8e-7444e148a29d'	System	12 Aug 2020 17:02:43
User entered 'No (N)'	System	12 Aug 2020 17:02:43

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:04:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-12T12:02:37', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '0728c952-02de-4247-aa8e-7444e148a29d'	System	12 Aug 2020 17:02:43
User entered 'None (1)'	System	12 Aug 2020 17:02:43

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-12T12:02:40', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '0728c952-02de-4247-aa8e-7444e148a29d'	System	12 Aug 2020 17:02:43
User entered '12 Aug 2020 12:02'	System	12 Aug 2020 17:02:43

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered 'Day 3'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:04:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-13T12:46:58', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '7af7cda8-1a44-480d-b9fb-cde5eea57122'	System	13 Aug 2020 17:47:23
User entered 'None (1)'	System	13 Aug 2020 17:47:23

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:04:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-13T12:47:03', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '7af7cda8-1a44-480d-b9fb-cde5eea57122'	System	13 Aug 2020 17:47:23
User entered 'No (N)'	System	13 Aug 2020 17:47:23

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-13T12:47:09', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '7af7cda8-1a44-480d-b9fb-cde5eea57122'	System	13 Aug 2020 17:47:23
User entered 'No (N)'	System	13 Aug 2020 17:47:23

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:04:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-13T12:47:16', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '7af7cda8-1a44-480d-b9fb-cde5eea57122'	System	13 Aug 2020 17:47:23
User entered 'None (1)'	System	13 Aug 2020 17:47:23

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-13T12:47:19', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '7af7cda8-1a44-480d-b9fb-cde5eea57122'	System	13 Aug 2020 17:47:23
User entered '13 Aug 2020 12:47'	System	13 Aug 2020 17:47:23

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered 'Day 4'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:04:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-14T12:10:11', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '56dde918-5acb-42a7-aaaa-c9b52221568b'	System	14 Aug 2020 17:10:36
User entered 'None (1)'	System	14 Aug 2020 17:10:36

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:04:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-14T12:10:14', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '56dde918-5acb-42a7-aaaa-c9b52221568b'	System	14 Aug 2020 17:10:36
User entered 'No (N)'	System	14 Aug 2020 17:10:36

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-14T12:10:19', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '56dde918-5acb-42a7-aaaa-c9b52221568b'	System	14 Aug 2020 17:10:36
User entered 'No (N)'	System	14 Aug 2020 17:10:36

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:04:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-14T12:10:29', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '56dde918-5acb-42a7-aaaa-c9b52221568b'	System	14 Aug 2020 17:10:36
User entered 'None (1)'	System	14 Aug 2020 17:10:36

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-14T12:10:32', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '56dde918-5acb-42a7-acaa-c9b52221568b'	System	14 Aug 2020 17:10:36
User entered '14 Aug 2020 12:10'	System	14 Aug 2020 17:10:36

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered 'Day 5'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:04:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-15T12:52:01', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '23392fd3-60f9-425c-99b4-d816844c70e2'	System	15 Aug 2020 17:52:21
User entered 'None (1)'	System	15 Aug 2020 17:52:21

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:04:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-15T12:52:04', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '23392fd3-60f9-425c-99b4-d816844c70e2'	System	15 Aug 2020 17:52:21
User entered 'No (N)'	System	15 Aug 2020 17:52:21

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-15T12:52:07', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '23392fd3-60f9-425c-99b4-d816844c70e2'	System	15 Aug 2020 17:52:21
User entered 'No (N)'	System	15 Aug 2020 17:52:21

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:04:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-15T12:52:15', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '23392fd3-60f9-425c-99b4-d816844c70e2'	System	15 Aug 2020 17:52:21
User entered 'None (1)'	System	15 Aug 2020 17:52:21

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-15T12:52:17', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '23392fd3-60f9-425c-99b4-d816844c70e2'	System	15 Aug 2020 17:52:21
User entered '15 Aug 2020 12:52'	System	15 Aug 2020 17:52:21

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered 'Day 6'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:04:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-16T12:25:18', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'af693190-e76c-4533-822f-7c4e66339a45'	System	16 Aug 2020 17:25:36
User entered 'None (1)'	System	16 Aug 2020 17:25:36

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:04:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-16T12:25:22', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'af693190-e76c-4533-822f-7c4e66339a45'	System	16 Aug 2020 17:25:36
User entered 'No (N)'	System	16 Aug 2020 17:25:36

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-16T12:25:26', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'af693190-e76c-4533-822f-7c4e66339a45'	System	16 Aug 2020 17:25:36
User entered 'No (N)'	System	16 Aug 2020 17:25:36

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:04:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-16T12:25:30', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'af693190-e76c-4533-822f-7c4e66339a45'	System	16 Aug 2020 17:25:36
User entered 'None (1)'	System	16 Aug 2020 17:25:36

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-16T12:25:33', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'af693190-e76c-4533-822f-7c4e66339a45'	System	16 Aug 2020 17:25:36
User entered '16 Aug 2020 12:25'	System	16 Aug 2020 17:25:36

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered 'Day 7'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:04:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-17T12:03:51', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'd69fc6f2-3fb4-433a-a385-9ac2c73fa54b'	System	17 Aug 2020 17:04:08
User entered 'None (1)'	System	17 Aug 2020 17:04:08

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:04:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-17T12:03:55', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'd69fc6f2-3fb4-433a-a385-9ac2c73fa54b'	System	17 Aug 2020 17:04:08
User entered 'No (N)'	System	17 Aug 2020 17:04:08

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-17T12:03:58', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'd69fc6f2-3fb4-433a-a385-9ac2c73fa54b'	System	17 Aug 2020 17:04:08
User entered 'No (N)'	System	17 Aug 2020 17:04:08

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:04:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-17T12:04:01', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'd69fc6f2-3fb4-433a-a385-9ac2c73fa54b'	System	17 Aug 2020 17:04:08
User entered 'None (1)'	System	17 Aug 2020 17:04:08

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-17T12:04:04', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'd69fc6f2-3fb4-433a-a385-9ac2c73fa54b'	System	17 Aug 2020 17:04:08
User entered '17 Aug 2020 12:04'	System	17 Aug 2020 17:04:08

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-11T12:13:53', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'c5b1f2d8-51c2-409d-94f5-1707adc91b18'	System	11 Aug 2020 17:14:31
User entered 'None (0)'	System	11 Aug 2020 17:14:31

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-11T12:13:55', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'c5b1f2d8-51c2-409d-94f5-1707adc91b18'	System	11 Aug 2020 17:14:31
User entered 'None (0)'	System	11 Aug 2020 17:14:31

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-11T12:13:59', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'c5b1f2d8-51c2-409d-94f5-1707adc91b18'	System	11 Aug 2020 17:14:31
User entered 'None (0)'	System	11 Aug 2020 17:14:31

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-11T12:14:04', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'c5b1f2d8-51c2-409d-94f5-1707adc91b18'	System	11 Aug 2020 17:14:31
User entered 'None (0)'	System	11 Aug 2020 17:14:31

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-11T12:14:07', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'c5b1f2d8-51c2-409d-94f5-1707adc91b18'	System	11 Aug 2020 17:14:31
User entered 'None (0)'	System	11 Aug 2020 17:14:31

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-11T12:14:10', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'c5b1f2d8-51c2-409d-94f5-1707adc91b18'	System	11 Aug 2020 17:14:31
User entered 'None (0)'	System	11 Aug 2020 17:14:31

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-11T12:14:22', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'c5b1f2d8-51c2-409d-94f5-1707adc91b18'	System	11 Aug 2020 17:14:31
User entered 'No (N)'	System	11 Aug 2020 17:14:31

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-11T12:14:29', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'c5b1f2d8-51c2-409d-94f5-1707adc91b18'	System	11 Aug 2020 17:14:31
User entered '11 Aug 2020 12:14'	System	11 Aug 2020 17:14:31

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '11 Aug 2020 12:00'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '11 Aug 2020 14:30'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-11T16:15:03', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '1c4511a6-7b3f-4b59-9431-0966c6627b77'	System	11 Aug 2020 21:15:52
User entered 'None (0)'	System	11 Aug 2020 21:15:52

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-11T16:15:08', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '1c4511a6-7b3f-4b59-9431-0966c6627b77'	System	11 Aug 2020 21:15:52
User entered 'None (0)'	System	11 Aug 2020 21:15:52

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-11T16:15:12', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '1c4511a6-7b3f-4b59-9431-0966c6627b77'	System	11 Aug 2020 21:15:52
User entered 'None (0)'	System	11 Aug 2020 21:15:52

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-11T16:15:16', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '1c4511a6-7b3f-4b59-9431-0966c6627b77'	System	11 Aug 2020 21:15:52
User entered 'None (0)'	System	11 Aug 2020 21:15:52

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-11T16:15:19', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '1c4511a6-7b3f-4b59-9431-0966c6627b77'	System	11 Aug 2020 21:15:52
User entered 'None (0)'	System	11 Aug 2020 21:15:52

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-11T16:15:23', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '1c4511a6-7b3f-4b59-9431-0966c6627b77'	System	11 Aug 2020 21:15:52
User entered 'None (0)'	System	11 Aug 2020 21:15:52

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-11T16:15:45', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '1c4511a6-7b3f-4b59-9431-0966c6627b77'	System	11 Aug 2020 21:15:52
User entered 'No (N)'	System	11 Aug 2020 21:15:52

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-11T16:15:49', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '1c4511a6-7b3f-4b59-9431-0966c6627b77'	System	11 Aug 2020 21:15:52
User entered '11 Aug 2020 16:15'	System	11 Aug 2020 21:15:52

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '11 Aug 2020 15:25'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered 'Day 2'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-12T12:02:49', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '9bf2f231-50fb-432d-aa46-34f11068d0b9'	System	12 Aug 2020 17:03:20
User entered 'None (0)'	System	12 Aug 2020 17:03:20

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-12T12:02:52', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '9bf2f231-50fb-432d-aa46-34f11068d0b9'	System	12 Aug 2020 17:03:20
User entered 'None (0)'	System	12 Aug 2020 17:03:20

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-12T12:02:57', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '9bf2f231-50fb-432d-aa46-34f11068d0b9'	System	12 Aug 2020 17:03:20
User entered 'None (0)'	System	12 Aug 2020 17:03:20

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-12T12:03:00', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '9bf2f231-50fb-432d-aa46-34f11068d0b9'	System	12 Aug 2020 17:03:20
User entered 'None (0)'	System	12 Aug 2020 17:03:20

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-12T12:03:03', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '9bf2f231-50fb-432d-aa46-34f11068d0b9'	System	12 Aug 2020 17:03:20
User entered 'None (0)'	System	12 Aug 2020 17:03:20

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-12T12:03:06', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '9bf2f231-50fb-432d-aa46-34f11068d0b9'	System	12 Aug 2020 17:03:20
User entered 'None (0)'	System	12 Aug 2020 17:03:20

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-12T12:03:15', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '9bf2f231-50fb-432d-aa46-34f11068d0b9'	System	12 Aug 2020 17:03:20
User entered 'No (N)'	System	12 Aug 2020 17:03:20

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-12T12:03:18', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '9bf2f231-50fb-432d-aa46-34f11068d0b9'	System	12 Aug 2020 17:03:20
User entered '12 Aug 2020 12:03'	System	12 Aug 2020 17:03:20

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered 'Day 3'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-13T12:47:26', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '731f05ec-e9a4-4b72-a1c8-d25c2a71aa63'	System	13 Aug 2020 17:47:57
User entered 'None (0)'	System	13 Aug 2020 17:47:57

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-13T12:47:29', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '731f05ec-e9a4-4b72-a1c8-d25c2a71aa63'	System	13 Aug 2020 17:47:57
User entered 'None (0)'	System	13 Aug 2020 17:47:57

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-13T12:47:32', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '731f05ec-e9a4-4b72-a1c8-d25c2a71aa63'	System	13 Aug 2020 17:47:57
User entered 'None (0)'	System	13 Aug 2020 17:47:57

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-13T12:47:35', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '731f05ec-e9a4-4b72-a1c8-d25c2a71aa63'	System	13 Aug 2020 17:47:57
User entered 'None (0)'	System	13 Aug 2020 17:47:57

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-13T12:47:38', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '731f05ec-e9a4-4b72-a1c8-d25c2a71aa63'	System	13 Aug 2020 17:47:57
User entered 'None (0)'	System	13 Aug 2020 17:47:57

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-13T12:47:41', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '731f05ec-e9a4-4b72-a1c8-d25c2a71aa63'	System	13 Aug 2020 17:47:57
User entered 'None (0)'	System	13 Aug 2020 17:47:57

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-13T12:47:50', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '731f05ec-e9a4-4b72-a1c8-d25c2a71aa63'	System	13 Aug 2020 17:47:57
User entered 'No (N)'	System	13 Aug 2020 17:47:57

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-13T12:47:52', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '731f05ec-e9a4-4b72-a1c8-d25c2a71aa63'	System	13 Aug 2020 17:47:57
User entered '13 Aug 2020 12:47'	System	13 Aug 2020 17:47:57

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered 'Day 4'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-14T12:10:37', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ed72a49d-7106-4554-b3ac-c8cee1b7bca7'	System	14 Aug 2020 17:11:12
User entered 'None (0)'	System	14 Aug 2020 17:11:12

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-14T12:10:40', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ed72a49d-7106-4554-b3ac-c8cee1b7bca7'	System	14 Aug 2020 17:11:12
User entered 'None (0)'	System	14 Aug 2020 17:11:12

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-14T12:10:43', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ed72a49d-7106-4554-b3ac-c8cee1b7bca7'	System	14 Aug 2020 17:11:12
User entered 'None (0)'	System	14 Aug 2020 17:11:12

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-14T12:10:48', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ed72a49d-7106-4554-b3ac-c8cee1b7bca7'	System	14 Aug 2020 17:11:12
User entered 'None (0)'	System	14 Aug 2020 17:11:12

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-14T12:10:51', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ed72a49d-7106-4554-b3ac-c8cee1b7bca7'	System	14 Aug 2020 17:11:12
User entered 'None (0)'	System	14 Aug 2020 17:11:12

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-14T12:10:54', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ed72a49d-7106-4554-b3ac-c8cee1b7bca7'	System	14 Aug 2020 17:11:12
User entered 'None (0)'	System	14 Aug 2020 17:11:12

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-14T12:11:05', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ed72a49d-7106-4554-b3ac-c8cee1b7bca7'	System	14 Aug 2020 17:11:12
User entered 'No (N)'	System	14 Aug 2020 17:11:12

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-14T12:11:09', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ed72a49d-7106-4554-b3ac-c8cee1b7bca7'	System	14 Aug 2020 17:11:12
User entered '14 Aug 2020 12:11'	System	14 Aug 2020 17:11:12

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered 'Day 5'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-15T12:52:22', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'c6d58a4a-cd17-44f6-956e-7dde1cc13cb2'	System	15 Aug 2020 17:52:52
User entered 'None (0)'	System	15 Aug 2020 17:52:52

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-15T12:52:24', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'c6d58a4a-cd17-44f6-956e-7dde1cc13cb2'	System	15 Aug 2020 17:52:52
User entered 'None (0)'	System	15 Aug 2020 17:52:52

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-15T12:52:28', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'c6d58a4a-cd17-44f6-956e-7dde1cc13cb2'	System	15 Aug 2020 17:52:52
User entered 'None (0)'	System	15 Aug 2020 17:52:52

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-15T12:52:30', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'c6d58a4a-cd17-44f6-956e-7dde1cc13cb2'	System	15 Aug 2020 17:52:52
User entered 'None (0)'	System	15 Aug 2020 17:52:52

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-15T12:52:35', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'c6d58a4a-cd17-44f6-956e-7dde1cc13cb2'	System	15 Aug 2020 17:52:52
User entered 'None (0)'	System	15 Aug 2020 17:52:52

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-15T12:52:38', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'c6d58a4a-cd17-44f6-956e-7dde1cc13cb2'	System	15 Aug 2020 17:52:52
User entered 'None (0)'	System	15 Aug 2020 17:52:52

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-15T12:52:44', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'c6d58a4a-cd17-44f6-956e-7dde1cc13cb2'	System	15 Aug 2020 17:52:52
User entered 'No (N)'	System	15 Aug 2020 17:52:52

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-15T12:52:46', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'c6d58a4a-cd17-44f6-956e-7dde1cc13cb2'	System	15 Aug 2020 17:52:52
User entered '15 Aug 2020 12:52'	System	15 Aug 2020 17:52:52

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered 'Day 6'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-16T12:25:38', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ac098188-dd5d-4b7d-94cf-c85981575ab2'	System	16 Aug 2020 17:26:07
User entered 'None (0)'	System	16 Aug 2020 17:26:07

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-16T12:25:40', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ac098188-dd5d-4b7d-94cf-c85981575ab2'	System	16 Aug 2020 17:26:07
User entered 'None (0)'	System	16 Aug 2020 17:26:07

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-16T12:25:44', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ac098188-dd5d-4b7d-94cf-c85981575ab2'	System	16 Aug 2020 17:26:07
User entered 'None (0)'	System	16 Aug 2020 17:26:07

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-16T12:25:47', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ac098188-dd5d-4b7d-94cf-c85981575ab2'	System	16 Aug 2020 17:26:07
User entered 'None (0)'	System	16 Aug 2020 17:26:07

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-16T12:25:50', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ac098188-dd5d-4b7d-94cf-c85981575ab2'	System	16 Aug 2020 17:26:07
User entered 'None (0)'	System	16 Aug 2020 17:26:07

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-16T12:25:53', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ac098188-dd5d-4b7d-94cf-c85981575ab2'	System	16 Aug 2020 17:26:07
User entered 'None (0)'	System	16 Aug 2020 17:26:07

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-16T12:26:00', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ac098188-dd5d-4b7d-94cf-c85981575ab2'	System	16 Aug 2020 17:26:07
User entered 'No (N)'	System	16 Aug 2020 17:26:07

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-16T12:26:03', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ac098188-dd5d-4b7d-94cf-c85981575ab2'	System	16 Aug 2020 17:26:07
User entered '16 Aug 2020 12:26'	System	16 Aug 2020 17:26:07

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered 'Day 7'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-17T12:04:08', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '78177330-940d-4af8-a3fb-2ae274c43313'	System	17 Aug 2020 17:04:42
User entered 'None (0)'	System	17 Aug 2020 17:04:42

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-17T12:04:10', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '78177330-940d-4af8-a3fb-2ae274c43313'	System	17 Aug 2020 17:04:42
User entered 'None (0)'	System	17 Aug 2020 17:04:42

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-17T12:04:13', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '78177330-940d-4af8-a3fb-2ae274c43313'	System	17 Aug 2020 17:04:42
User entered 'None (0)'	System	17 Aug 2020 17:04:42

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-17T12:04:16', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '78177330-940d-4af8-a3fb-2ae274c43313'	System	17 Aug 2020 17:04:42
User entered 'None (0)'	System	17 Aug 2020 17:04:42

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-17T12:04:18', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '78177330-940d-4af8-a3fb-2ae274c43313'	System	17 Aug 2020 17:04:42
User entered 'None (0)'	System	17 Aug 2020 17:04:42

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-17T12:04:27', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '78177330-940d-4af8-a3fb-2ae274c43313'	System	17 Aug 2020 17:04:42
User entered 'None (0)'	System	17 Aug 2020 17:04:42

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-17T12:04:34', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '78177330-940d-4af8-a3fb-2ae274c43313'	System	17 Aug 2020 17:04:42
User entered 'No (N)'	System	17 Aug 2020 17:04:42

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-08-17T12:04:37', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '78177330-940d-4af8-a3fb-2ae274c43313'	System	17 Aug 2020 17:04:42
User entered '17 Aug 2020 12:04'	System	17 Aug 2020 17:04:42

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 16:46:41

US3552005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 16:46:41

US3552005

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	25 Aug 2020 15:21:42

US3552005

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '18 Aug 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	25 Aug 2020 15:21:42

US3552005

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'Contact Made (CONTACT MADE)'	Mikayla Frye (b) (4) (b) (4)	25 Aug 2020 15:21:42

US3552005

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered empty.	Mikayla Frye (b) (4) (b) (4)	25 Aug 2020 15:21:42

US3552005

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	25 Aug 2020 15:21:46

US3552005

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User entered 'l'	System	25 Aug 2020 15:21:46

US3552005

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	25 Aug 2020 15:22:01

US3552005

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '25 Aug 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	25 Aug 2020 15:22:01

US3552005

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'Contact Made (CONTACT MADE)'	Mikayla Frye (b) (4) (b) (4)	25 Aug 2020 15:22:01

US3552005

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered empty.	Mikayla Frye (b) (4) (b) (4)	25 Aug 2020 15:22:01

US3552005

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Sep 2020 16:41:06

US3552005

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User entered 'I'	System	01 Sep 2020 16:41:06

US3552005

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Sep 2020 16:41:17

US3552005

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '1 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Sep 2020 16:41:17

US3552005

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	01 Sep 2020 16:41:17

US3552005

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered empty.	Stanley Dublin (b) (4) (b) (4)	01 Sep 2020 16:41:17

US3552005

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	Janice Tennant (b) (4) (b) (4)	07 Sep 2020 13:22:42

US3552005

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User entered 'l'	System	07 Sep 2020 13:22:42

US3552005

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:04:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	Janice Tennant (b) (4) [REDACTED]	07 Sep 2020 13:54:46

US3552005

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:04:59

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User closed query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 04:43:24
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'within approved window period per protocol' (Site from System).	Janice Tennant (b) (4)	07 Sep 2020 13:55:47
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	07 Sep 2020 13:54:46
User entered '7 Sep 2020'	Janice Tennant (b) (4)	07 Sep 2020 13:54:46

US3552005

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Clinic (Clinic)'	(b) (4) Janice Tennant (b) (4)	07 Sep 2020 13:54:46

US3552005

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:04:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered 'VISIT2'	System	07 Sep 2020 13:54:46

US3552005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	07 Sep 2020 14:55:31

US3552005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 14:55:31

US3552005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '7 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 14:55:31

US3552005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered '08:00'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 14:55:31

US3552005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered '7 Sep 2020 08:00'	System	07 Sep 2020 14:55:31

US3552005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered '98' F	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 14:55:31

US3552005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 14:55:31

US3552005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 14:55:31

US3552005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered '72'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 14:55:31

US3552005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered 'bpm'	System	07 Sep 2020 14:55:31

US3552005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered '16'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 14:55:31

US3552005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered 'breaths/min'	System	07 Sep 2020 14:55:31

US3552005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered '127'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 14:55:31

US3552005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered 'mmHg'	System	07 Sep 2020 14:55:31

US3552005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered '70'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 14:55:31

US3552005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered 'mmHg'	System	07 Sep 2020 14:55:31

US3552005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	07 Sep 2020 14:56:09

US3552005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 14:56:09

US3552005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '7 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 14:56:09

US3552005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered '09:28'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 14:56:09

US3552005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered '7 Sep 2020 09:28'	System	07 Sep 2020 14:56:09

US3552005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered '98.3' F	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 14:56:09

US3552005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 14:56:09

US3552005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered empty.	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 14:56:09

US3552005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered '73'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 14:56:09

US3552005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered 'bpm'	System	07 Sep 2020 14:56:09

US3552005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered '16'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 14:56:09

US3552005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered 'breaths/min'	System	07 Sep 2020 14:56:09

US3552005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered '113'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 14:56:09

US3552005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered 'mmHg'	System	07 Sep 2020 14:56:09

US3552005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered '72'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 14:56:09

US3552005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered 'mmHg'	System	07 Sep 2020 14:56:09

US3552005

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:04:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 14:56:20

US3552005

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:04:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '7 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 14:56:20

US3552005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	Janice Tennant (b) (4) (b) (4)	07 Sep 2020 13:54:23

US3552005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered empty.	Janice Tennant (b) (4) (b) (4)	07 Sep 2020 13:54:23

US3552005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Janice Tennant (b) (4)	07 Sep 2020 13:54:23

US3552005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered 'MRNA-1273 OR PLACEBO'	System	07 Sep 2020 13:54:23

US3552005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '7 Sep 2020'	(b) (4) Janice Tennant (b) (4)	07 Sep 2020 13:54:23

US3552005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '08:48'	(b) (4) Janice Tennant (b) (4)	07 Sep 2020 13:54:23

US3552005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered '7 Sep 2020 08:48'	System	07 Sep 2020 13:54:23

US3552005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Left Arm (LEFT ARM)'	(b) (4) Janice Tennant (b) (4)	07 Sep 2020 13:54:23

US3552005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered 'ONCE'	System	07 Sep 2020 13:54:23

US3552005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered 'INTRAMUSCULAR'	System	07 Sep 2020 13:54:23

US3552005

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 14:57:02

US3552005

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '7 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 14:57:02

US3552005

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered '8:20'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 14:57:02

US3552005

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered '7 Sep 2020 8:20'	System	07 Sep 2020 14:57:02

US3552005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:04:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '7 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 14:57:15

US3552005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:04:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stanley Doublin (b) (4) (b) (4)	07 Sep 2020 14:57:15

US3552005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:04:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 14:57:15

US3552005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:04:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '08:21'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 14:57:15

US3552005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:04:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered '7 Sep 2020 08:21'	System	07 Sep 2020 14:57:15

US3552005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:04:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stanley Doublin (b) (4) (b) (4)	07 Sep 2020 14:57:15

US3552005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:04:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 14:57:15

US3552005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:04:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 14:57:15

US3552005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:04:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered empty.	System	07 Sep 2020 14:57:15

US3552005

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Stanley Dublin (b) (4)	22 Sep 2020 19:13:20
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Stanley Dublin (b) (4)	22 Sep 2020 19:12:45
User entered 'Yes (Y)'	(b) (4)	
	Stanley Dublin (b) (4)	15 Sep 2020 18:24:39
	(b) (4)	

US3552005

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered '1'	System	22 Sep 2020 19:13:20
User entered empty.	System	22 Sep 2020 19:12:45
User entered '1'	System	15 Sep 2020 18:24:39

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	07 Sep 2020 13:54:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-07T09:18:57', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'a921654e-cb45-4a4c-ad89-b6f00d285953'	System	07 Sep 2020 14:19:22
User entered 'Yes (Y)'	System	07 Sep 2020 14:19:22

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-07T09:19:05', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'a921654e-cb45-4a4c-ad89-b6f00d285953'	System	07 Sep 2020 14:19:22
User entered '98.3'	System	07 Sep 2020 14:19:22

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-07T09:19:12', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'a921654e-cb45-4a4c-ad89-b6f00d285953'	System	07 Sep 2020 14:19:22
User entered 'No (N)'	System	07 Sep 2020 14:19:22

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-07T09:19:18', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'a921654e-cb45-4a4c-ad89-b6f00d285953'	System	07 Sep 2020 14:19:22
User entered '07 Sep 2020 09:19'	System	07 Sep 2020 14:19:22

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '07 Sep 2020 09:08'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '07 Sep 2020 11:38'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	07 Sep 2020 13:54:23
User entered 'Day 1, after vaccination (at home)'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-07T19:31:32', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '3c3b952b-f98a-4480-bac6-0012d4b1f942'	System	08 Sep 2020 00:31:54
User entered 'Yes (Y)'	System	08 Sep 2020 00:31:54

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-07T19:31:41', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '3c3b952b-f98a-4480-bac6-0012d4b1f942'	System	08 Sep 2020 00:31:54
User entered '98.5'	System	08 Sep 2020 00:31:54

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-07T19:31:46', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '3c3b952b-f98a-4480-bac6-0012d4b1f942'	System	08 Sep 2020 00:31:54
User entered 'No (N)'	System	08 Sep 2020 00:31:54

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-07T19:31:51', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '3c3b952b-f98a-4480-bac6-0012d4b1f942'	System	08 Sep 2020 00:31:54
User entered '07 Sep 2020 19:31'	System	08 Sep 2020 00:31:54

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '07 Sep 2020 12:33'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '08 Sep 2020 11:59'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	07 Sep 2020 13:54:23
User entered 'Day 2'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:04:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-08T12:46:46', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '7c8060e1-4858-4f38-9d24-3712cc04cf98'	System	08 Sep 2020 17:47:18
User entered 'Yes (Y)'	System	08 Sep 2020 17:47:18

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:04:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-08T12:46:55', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '7c8060e1-4858-4f38-9d24-3712cc04cf98'	System	08 Sep 2020 17:47:18
User entered '97.8'	System	08 Sep 2020 17:47:18

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-08T12:46:59', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '7c8060e1-4858-4f38-9d24-3712cc04cf98'	System	08 Sep 2020 17:47:18
User entered 'No (N)'	System	08 Sep 2020 17:47:18

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-08T12:47:06', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '7c8060e1-4858-4f38-9d24-3712cc04cf98'	System	08 Sep 2020 17:47:18
User entered '08 Sep 2020 12:47'	System	08 Sep 2020 17:47:18

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	07 Sep 2020 13:54:23
User entered 'Day 3'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:04:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-09T12:11:51', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '29b9ec34-a50f-4ab5-b5a5-a631494cd346'	System	09 Sep 2020 17:13:02
User entered 'Yes (Y)'	System	09 Sep 2020 17:13:02

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:04:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-09T12:12:31', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '29b9ec34-a50f-4ab5-b5a5-a631494cd346'	System	09 Sep 2020 17:13:02
User entered '98.2'	System	09 Sep 2020 17:13:02

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-09T12:12:52', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '29b9ec34-a50f-4ab5-b5a5-a631494cd346'	System	09 Sep 2020 17:13:02
User entered 'No (N)'	System	09 Sep 2020 17:13:02

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-09T12:12:57', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '29b9ec34-a50f-4ab5-b5a5-a631494cd346'	System	09 Sep 2020 17:13:02
User entered '09 Sep 2020 12:12'	System	09 Sep 2020 17:13:02

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	07 Sep 2020 13:54:23
User entered 'Day 4'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:04:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-10T12:20:04', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '2adc816b-408c-47b8-9155-a22b372f0d51'	System	10 Sep 2020 17:20:40
User entered 'Yes (Y)'	System	10 Sep 2020 17:20:40

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:04:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-10T12:20:12', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '2adc816b-408c-47b8-9155-a22b372f0d51'	System	10 Sep 2020 17:20:40
User entered '97.6'	System	10 Sep 2020 17:20:40

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-10T12:20:20', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '2adc816b-408c-47b8-9155-a22b372f0d51'	System	10 Sep 2020 17:20:40
User entered 'No (N)'	System	10 Sep 2020 17:20:40

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-10T12:20:31', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '2adc816b-408c-47b8-9155-a22b372f0d51'	System	10 Sep 2020 17:20:40
User entered '10 Sep 2020 12:20'	System	10 Sep 2020 17:20:40

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '10 Sep 2020 12:00'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '11 Sep 2020 11:59'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	07 Sep 2020 13:54:23
User entered 'Day 5'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:04:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-11T14:11:58', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'b880d3c9-fb43-4346-9d61-7db84ddf7741'	System	11 Sep 2020 19:12:26
User entered 'Yes (Y)'	System	11 Sep 2020 19:12:26

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:04:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-11T14:12:04', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'b880d3c9-fb43-4346-9d61-7db84ddf7741'	System	11 Sep 2020 19:12:26
User entered '98.0'	System	11 Sep 2020 19:12:26

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-11T14:12:08', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'b880d3c9-fb43-4346-9d61-7db84ddf7741'	System	11 Sep 2020 19:12:26
User entered 'No (N)'	System	11 Sep 2020 19:12:26

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-11T14:12:12', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'b880d3c9-fb43-4346-9d61-7db84ddf7741'	System	11 Sep 2020 19:12:26
User entered '11 Sep 2020 14:12'	System	11 Sep 2020 19:12:26

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '11 Sep 2020 12:00'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '12 Sep 2020 11:59'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	07 Sep 2020 13:54:23
User entered 'Day 6'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:04:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-12T12:53:00', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ae4d7e5c-0cab-41d3-b4a8-0064a666a096'	System	12 Sep 2020 17:53:16
User entered 'Yes (Y)'	System	12 Sep 2020 17:53:16

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:04:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-12T12:53:07', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ae4d7e5c-0cab-41d3-b4a8-0064a666a096'	System	12 Sep 2020 17:53:16
User entered '98.4'	System	12 Sep 2020 17:53:16

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-12T12:53:11', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ae4d7e5c-0cab-41d3-b4a8-0064a666a096'	System	12 Sep 2020 17:53:16
User entered 'No (N)'	System	12 Sep 2020 17:53:16

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-12T12:53:14', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ae4d7e5c-0cab-41d3-b4a8-0064a666a096'	System	12 Sep 2020 17:53:16
User entered '12 Sep 2020 12:53'	System	12 Sep 2020 17:53:16

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '12 Sep 2020 12:00'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '13 Sep 2020 11:59'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	07 Sep 2020 13:54:23
User entered 'Day 7'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:04:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-13T13:11:08', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'e0b82f2e-91ed-44cc-b0f6-467c5000da3e'	System	13 Sep 2020 18:11:39
User entered 'Yes (Y)'	System	13 Sep 2020 18:11:39

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:04:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-13T13:11:22', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'e0b82f2e-91ed-44cc-b0f6-467c5000da3e'	System	13 Sep 2020 18:11:39
User entered '97.3'	System	13 Sep 2020 18:11:39

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-13T13:11:33', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'e0b82f2e-91ed-44cc-b0f6-467c5000da3e'	System	13 Sep 2020 18:11:39
User entered 'No (N)'	System	13 Sep 2020 18:11:39

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-13T13:11:35', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'e0b82f2e-91ed-44cc-b0f6-467c5000da3e'	System	13 Sep 2020 18:11:39
User entered '13 Sep 2020 13:11'	System	13 Sep 2020 18:11:39

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '13 Sep 2020 12:00'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '14 Sep 2020 11:59'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	07 Sep 2020 13:54:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-07T09:19:26', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '06d313ff-7432-4711-a6cc-9c9d14bf6573'	System	07 Sep 2020 14:19:54
User entered 'None (1)'	System	07 Sep 2020 14:19:54

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-07T09:19:33', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '06d313ff-7432-4711-a6cc-9c9d14bf6573'	System	07 Sep 2020 14:19:54
User entered 'No (N)'	System	07 Sep 2020 14:19:54

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-07T09:19:36', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '06d313ff-7432-4711-a6cc-9c9d14bf6573'	System	07 Sep 2020 14:19:54
User entered 'No (N)'	System	07 Sep 2020 14:19:54

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-07T09:19:48', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '06d313ff-7432-4711-a6cc-9c9d14bf6573'	System	07 Sep 2020 14:19:54
User entered 'None (1)'	System	07 Sep 2020 14:19:54

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-07T09:19:51', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '06d313ff-7432-4711-a6cc-9c9d14bf6573'	System	07 Sep 2020 14:19:54
User entered '07 Sep 2020 09:19'	System	07 Sep 2020 14:19:54

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '07 Sep 2020 09:08'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '07 Sep 2020 11:38'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	07 Sep 2020 13:54:23
User entered 'Day 1, after vaccination (at home)'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-07T19:32:17', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'eb9b669e-d20b-4a2e-a136-450e7919e9f1'	System	08 Sep 2020 00:33:28
User entered 'Does not interfere with activity (2)'	System	08 Sep 2020 00:33:28

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-07T19:32:21', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'eb9b669e-d20b-4a2e-a136-450e7919e9f1'	System	08 Sep 2020 00:33:28
User entered 'No (N)'	System	08 Sep 2020 00:33:28

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-07T19:32:43', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'eb9b669e-d20b-4a2e-a136-450e7919e9f1'	System	08 Sep 2020 00:33:28
User entered 'No (N)'	System	08 Sep 2020 00:33:28

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-07T19:33:18', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'eb9b669e-d20b-4a2e-a136-450e7919e9f1'	System	08 Sep 2020 00:33:28
User entered 'None (1)'	System	08 Sep 2020 00:33:28

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-07T19:33:23', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'eb9b669e-d20b-4a2e-a136-450e7919e9f1'	System	08 Sep 2020 00:33:28
User entered '07 Sep 2020 19:33'	System	08 Sep 2020 00:33:28

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '07 Sep 2020 12:33'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '08 Sep 2020 11:59'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	07 Sep 2020 13:54:23
User entered 'Day 2'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:04:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-08T12:47:16', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '984bffd7-d901-425c-be7b-9b2a6a616294'	System	08 Sep 2020 17:47:52
User entered 'Does not interfere with activity (2)'	System	08 Sep 2020 17:47:52

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:04:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-08T12:47:19', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '984bfd7-d901-425c-be7b-9b2a6a616294'	System	08 Sep 2020 17:47:52
User entered 'No (N)'	System	08 Sep 2020 17:47:52

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-08T12:47:22', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '984bfd7-d901-425c-be7b-9b2a6a616294'	System	08 Sep 2020 17:47:52
User entered 'No (N)'	System	08 Sep 2020 17:47:52

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:04:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-08T12:47:45', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '984bffd7-d901-425c-be7b-9b2a6a616294'	System	08 Sep 2020 17:47:52
User entered 'None (1)'	System	08 Sep 2020 17:47:52

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-08T12:47:48', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '984bffd7-d901-425c-be7b-9b2a6a616294'	System	08 Sep 2020 17:47:52
User entered '08 Sep 2020 12:47'	System	08 Sep 2020 17:47:52

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	07 Sep 2020 13:54:23
User entered 'Day 3'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:04:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-09T12:13:05', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '329c871f-06fa-41c9-9de5-ddfba099e0c4'	System	09 Sep 2020 17:13:28
User entered 'None (1)'	System	09 Sep 2020 17:13:28

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:04:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-09T12:13:08', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '329c871f-06fa-41c9-9de5-ddfba099e0c4'	System	09 Sep 2020 17:13:28
User entered 'No (N)'	System	09 Sep 2020 17:13:28

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-09T12:13:11', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '329c871f-06fa-41c9-9de5-ddfba099e0c4'	System	09 Sep 2020 17:13:28
User entered 'No (N)'	System	09 Sep 2020 17:13:28

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:04:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-09T12:13:20', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '329c871f-06fa-41c9-9de5-ddfba099e0c4'	System	09 Sep 2020 17:13:28
User entered 'None (1)'	System	09 Sep 2020 17:13:28

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-09T12:13:22', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '329c871f-06fa-41c9-9de5-ddfba099e0c4'	System	09 Sep 2020 17:13:28
User entered '09 Sep 2020 12:13'	System	09 Sep 2020 17:13:28

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	07 Sep 2020 13:54:23
User entered 'Day 4'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:04:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-10T12:20:44', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'bb05714c-3010-44da-9390-ab07a1e7b035'	System	10 Sep 2020 17:21:06
User entered 'None (1)'	System	10 Sep 2020 17:21:06

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:04:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-10T12:20:47', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'bb05714c-3010-44da-9390-ab07a1e7b035'	System	10 Sep 2020 17:21:06
User entered 'No (N)'	System	10 Sep 2020 17:21:06

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-10T12:20:50', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'bb05714c-3010-44da-9390-ab07a1e7b035'	System	10 Sep 2020 17:21:06
User entered 'No (N)'	System	10 Sep 2020 17:21:06

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:04:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-10T12:21:00', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'bb05714c-3010-44da-9390-ab07a1e7b035'	System	10 Sep 2020 17:21:06
User entered 'None (1)'	System	10 Sep 2020 17:21:06

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-10T12:21:02', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'bb05714c-3010-44da-9390-ab07a1e7b035'	System	10 Sep 2020 17:21:06
User entered '10 Sep 2020 12:21'	System	10 Sep 2020 17:21:06

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '10 Sep 2020 12:00'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '11 Sep 2020 11:59'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	07 Sep 2020 13:54:23
User entered 'Day 5'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:04:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-11T14:12:15', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '23a9dcd7-3740-41b8-8988-cedf67ec0117'	System	11 Sep 2020 19:12:54
User entered 'None (1)'	System	11 Sep 2020 19:12:54

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:04:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-11T14:12:18', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '23a9dcd7-3740-41b8-8988-cedf67ec0117'	System	11 Sep 2020 19:12:54
User entered 'No (N)'	System	11 Sep 2020 19:12:54

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-11T14:12:21', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '23a9dcd7-3740-41b8-8988-cedf67ec0117'	System	11 Sep 2020 19:12:54
User entered 'No (N)'	System	11 Sep 2020 19:12:54

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:04:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-11T14:12:31', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '23a9dcd7-3740-41b8-8988-cedf67ec0117'	System	11 Sep 2020 19:12:54
User entered 'None (1)'	System	11 Sep 2020 19:12:54

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-11T14:12:34', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '23a9dcd7-3740-41b8-8988-cedf67ec0117'	System	11 Sep 2020 19:12:54
User entered '11 Sep 2020 14:12'	System	11 Sep 2020 19:12:54

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '11 Sep 2020 12:00'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '12 Sep 2020 11:59'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	07 Sep 2020 13:54:23
User entered 'Day 6'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:04:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-12T12:53:19', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ee0f79ac-8f3b-4a6d-aa95-140b8264a545'	System	12 Sep 2020 17:53:38
User entered 'None (1)'	System	12 Sep 2020 17:53:38

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:04:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-12T12:53:21', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ee0f79ac-8f3b-4a6d-aa95-140b8264a545'	System	12 Sep 2020 17:53:38
User entered 'No (N)'	System	12 Sep 2020 17:53:38

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-12T12:53:25', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ee0f79ac-8f3b-4a6d-aa95-140b8264a545'	System	12 Sep 2020 17:53:38
User entered 'No (N)'	System	12 Sep 2020 17:53:38

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:04:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-12T12:53:33', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ee0f79ac-8f3b-4a6d-aa95-140b8264a545'	System	12 Sep 2020 17:53:38
User entered 'None (1)'	System	12 Sep 2020 17:53:38

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-12T12:53:35', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ee0f79ac-8f3b-4a6d-aa95-140b8264a545'	System	12 Sep 2020 17:53:38
User entered '12 Sep 2020 12:53'	System	12 Sep 2020 17:53:38

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '12 Sep 2020 12:00'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '13 Sep 2020 11:59'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	07 Sep 2020 13:54:23
User entered 'Day 7'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:04:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-13T13:11:39', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ec20ed3a-28ea-4574-acf9-b3d5e8e3e0e5'	System	13 Sep 2020 18:12:30
User entered 'None (1)'	System	13 Sep 2020 18:12:30

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:04:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-13T13:11:42', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ec20ed3a-28ea-4574-acf9-b3d5e8e3e0e5'	System	13 Sep 2020 18:12:30
User entered 'No (N)'	System	13 Sep 2020 18:12:30

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-13T13:11:45', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ec20ed3a-28ea-4574-acf9-b3d5e8e3e0e5'	System	13 Sep 2020 18:12:30
User entered 'No (N)'	System	13 Sep 2020 18:12:30

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:04:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-13T13:11:52', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ec20ed3a-28ea-4574-acf9-b3d5e8e3e0e5'	System	13 Sep 2020 18:12:30
User entered 'None (1)'	System	13 Sep 2020 18:12:30

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-13T13:11:54', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ec20ed3a-28ea-4574-acf9-b3d5e8e3e0e5'	System	13 Sep 2020 18:12:30
User entered '13 Sep 2020 13:11'	System	13 Sep 2020 18:12:30

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '13 Sep 2020 12:00'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '14 Sep 2020 11:59'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	07 Sep 2020 13:54:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-07T09:19:56', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ab62749d-3589-4ad3-be97-19b79338ea12'	System	07 Sep 2020 14:20:28
User entered 'None (0)'	System	07 Sep 2020 14:20:28

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-07T09:19:58', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ab62749d-3589-4ad3-be97-19b79338ea12'	System	07 Sep 2020 14:20:28
User entered 'None (0)'	System	07 Sep 2020 14:20:28

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-07T09:20:01', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ab62749d-3589-4ad3-be97-19b79338ea12'	System	07 Sep 2020 14:20:28
User entered 'None (0)'	System	07 Sep 2020 14:20:28

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-07T09:20:04', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ab62749d-3589-4ad3-be97-19b79338ea12'	System	07 Sep 2020 14:20:28
User entered 'None (0)'	System	07 Sep 2020 14:20:28

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-07T09:20:06', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ab62749d-3589-4ad3-be97-19b79338ea12'	System	07 Sep 2020 14:20:28
User entered 'None (0)'	System	07 Sep 2020 14:20:28

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-07T09:20:09', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ab62749d-3589-4ad3-be97-19b79338ea12'	System	07 Sep 2020 14:20:28
User entered 'None (0)'	System	07 Sep 2020 14:20:28

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-07T09:20:22', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ab62749d-3589-4ad3-be97-19b79338ea12'	System	07 Sep 2020 14:20:28
User entered 'No (N)'	System	07 Sep 2020 14:20:28

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-07T09:20:24', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ab62749d-3589-4ad3-be97-19b79338ea12'	System	07 Sep 2020 14:20:28
User entered '07 Sep 2020 09:20'	System	07 Sep 2020 14:20:28

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '07 Sep 2020 09:08'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '07 Sep 2020 11:38'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	07 Sep 2020 13:54:23
User entered 'Day 1, after vaccination (at home)'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-07T19:33:31', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '76f03f07-b340-440a-b275-743d58aa035b'	System	08 Sep 2020 00:34:25
User entered 'None (0)'	System	08 Sep 2020 00:34:25

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-07T19:33:37', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '76f03f07-b340-440a-b275-743d58aa035b'	System	08 Sep 2020 00:34:25
User entered 'No interference with activity (1)'	System	08 Sep 2020 00:34:25

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-07T19:33:48', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '76f03f07-b340-440a-b275-743d58aa035b'	System	08 Sep 2020 00:34:25
User entered 'None (0)'	System	08 Sep 2020 00:34:25

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-07T19:33:56', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '76f03f07-b340-440a-b275-743d58aa035b'	System	08 Sep 2020 00:34:25
User entered 'None (0)'	System	08 Sep 2020 00:34:25

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-07T19:34:00', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '76f03f07-b340-440a-b275-743d58aa035b'	System	08 Sep 2020 00:34:25
User entered 'None (0)'	System	08 Sep 2020 00:34:25

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-07T19:34:04', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '76f03f07-b340-440a-b275-743d58aa035b'	System	08 Sep 2020 00:34:25
User entered 'None (0)'	System	08 Sep 2020 00:34:25

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-07T19:34:15', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '76f03f07-b340-440a-b275-743d58aa035b'	System	08 Sep 2020 00:34:25
User entered 'No (N)'	System	08 Sep 2020 00:34:25

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-07T19:34:18', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '76f03f07-b340-440a-b275-743d58aa035b'	System	08 Sep 2020 00:34:25
User entered '07 Sep 2020 19:34'	System	08 Sep 2020 00:34:25

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '07 Sep 2020 12:33'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '08 Sep 2020 11:59'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	07 Sep 2020 13:54:23
User entered 'Day 2'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-08T12:47:53', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'cec381eb-36dd-426c-948c-a8d604e6292a'	System	08 Sep 2020 17:48:36
User entered 'None (0)'	System	08 Sep 2020 17:48:36

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-08T12:47:56', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'cec381eb-36dd-426c-948c-a8d604e6292a'	System	08 Sep 2020 17:48:36
User entered 'No interference with activity (1)'	System	08 Sep 2020 17:48:36

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-08T12:48:03', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'cec381eb-36dd-426c-948c-a8d604e6292a'	System	08 Sep 2020 17:48:36
User entered 'None (0)'	System	08 Sep 2020 17:48:36

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-08T12:48:14', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'cec381eb-36dd-426c-948c-a8d604e6292a'	System	08 Sep 2020 17:48:36
User entered 'None (0)'	System	08 Sep 2020 17:48:36

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-08T12:48:16', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'cec381eb-36dd-426c-948c-a8d604e6292a'	System	08 Sep 2020 17:48:36
User entered 'None (0)'	System	08 Sep 2020 17:48:36

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-08T12:48:22', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'cec381eb-36dd-426c-948c-a8d604e6292a'	System	08 Sep 2020 17:48:36
User entered 'None (0)'	System	08 Sep 2020 17:48:36

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-08T12:48:31', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'cec381eb-36dd-426c-948c-a8d604e6292a'	System	08 Sep 2020 17:48:36
User entered 'No (N)'	System	08 Sep 2020 17:48:36

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-08T12:48:33', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'cec381eb-36dd-426c-948c-a8d604e6292a'	System	08 Sep 2020 17:48:36
User entered '08 Sep 2020 12:48'	System	08 Sep 2020 17:48:36

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	07 Sep 2020 13:54:23
User entered 'Day 3'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-09T12:13:52', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '4e7a8ffb-1d37-4603-acad-9869a3bb6e44'	System	09 Sep 2020 17:14:25
User entered 'No interference with activity (1)'	System	09 Sep 2020 17:14:25

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-09T12:13:57', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '4e7a8ffb-1d37-4603-acad-9869a3bb6e44'	System	09 Sep 2020 17:14:25
User entered 'No interference with activity (1)'	System	09 Sep 2020 17:14:25

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-09T12:14:02', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '4e7a8ffb-1d37-4603-acad-9869a3bb6e44'	System	09 Sep 2020 17:14:25
User entered 'None (0)'	System	09 Sep 2020 17:14:25

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-09T12:14:05', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '4e7a8ffb-1d37-4603-acad-9869a3bb6e44'	System	09 Sep 2020 17:14:25
User entered 'None (0)'	System	09 Sep 2020 17:14:25

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-09T12:14:08', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '4e7a8ffb-1d37-4603-acad-9869a3bb6e44'	System	09 Sep 2020 17:14:25
User entered 'None (0)'	System	09 Sep 2020 17:14:25

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-09T12:14:11', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '4e7a8ffb-1d37-4603-acad-9869a3bb6e44'	System	09 Sep 2020 17:14:25
User entered 'None (0)'	System	09 Sep 2020 17:14:25

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-09T12:14:20', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '4e7a8ffb-1d37-4603-acad-9869a3bb6e44'	System	09 Sep 2020 17:14:25
User entered 'No (N)'	System	09 Sep 2020 17:14:25

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-09T12:14:22', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '4e7a8ffb-1d37-4603-acad-9869a3bb6e44'	System	09 Sep 2020 17:14:25
User entered '09 Sep 2020 12:14'	System	09 Sep 2020 17:14:25

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	07 Sep 2020 13:54:23
User entered 'Day 4'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-10T12:21:16', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'aad20ec8-dcd7-4bc3-a155-de07fd667503'	System	10 Sep 2020 17:21:40
User entered 'No interference with activity (1)'	System	10 Sep 2020 17:21:40

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-10T12:21:19', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'aad20ec8-dcd7-4bc3-a155-de07fd667503'	System	10 Sep 2020 17:21:40
User entered 'None (0)'	System	10 Sep 2020 17:21:40

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-10T12:21:21', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'aad20ec8-dcd7-4bc3-a155-de07fd667503'	System	10 Sep 2020 17:21:40
User entered 'None (0)'	System	10 Sep 2020 17:21:40

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-10T12:21:24', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'aad20ec8-dcd7-4bc3-a155-de07fd667503'	System	10 Sep 2020 17:21:40
User entered 'None (0)'	System	10 Sep 2020 17:21:40

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-10T12:21:27', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'aad20ec8-dcd7-4bc3-a155-de07fd667503'	System	10 Sep 2020 17:21:40
User entered 'None (0)'	System	10 Sep 2020 17:21:40

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-10T12:21:30', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'aad20ec8-dcd7-4bc3-a155-de07fd667503'	System	10 Sep 2020 17:21:40
User entered 'None (0)'	System	10 Sep 2020 17:21:40

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-10T12:21:34', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'aad20ec8-dcd7-4bc3-a155-de07fd667503'	System	10 Sep 2020 17:21:40
User entered 'No (N)'	System	10 Sep 2020 17:21:40

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-10T12:21:36', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'aad20ec8-dcd7-4bc3-a155-de07fd667503'	System	10 Sep 2020 17:21:40
User entered '10 Sep 2020 12:21'	System	10 Sep 2020 17:21:40

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '10 Sep 2020 12:00'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '11 Sep 2020 11:59'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	07 Sep 2020 13:54:23
User entered 'Day 5'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-11T14:12:39', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '92802bc5-d6fa-4507-b341-0d35689a097d'	System	11 Sep 2020 19:13:03
User entered 'None (0)'	System	11 Sep 2020 19:13:03

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-11T14:12:42', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '92802bc5-d6fa-4507-b341-0d35689a097d'	System	11 Sep 2020 19:13:03
User entered 'None (0)'	System	11 Sep 2020 19:13:03

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-11T14:12:44', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '92802bc5-d6fa-4507-b341-0d35689a097d'	System	11 Sep 2020 19:13:03
User entered 'None (0)'	System	11 Sep 2020 19:13:03

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-11T14:12:47', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '92802bc5-d6fa-4507-b341-0d35689a097d'	System	11 Sep 2020 19:13:03
User entered 'None (0)'	System	11 Sep 2020 19:13:03

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-11T14:12:49', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '92802bc5-d6fa-4507-b341-0d35689a097d'	System	11 Sep 2020 19:13:03
User entered 'None (0)'	System	11 Sep 2020 19:13:03

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-11T14:12:52', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '92802bc5-d6fa-4507-b341-0d35689a097d'	System	11 Sep 2020 19:13:03
User entered 'None (0)'	System	11 Sep 2020 19:13:03

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-11T14:12:54', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '92802bc5-d6fa-4507-b341-0d35689a097d'	System	11 Sep 2020 19:13:03
User entered 'No (N)'	System	11 Sep 2020 19:13:03

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-11T14:12:57', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '92802bc5-d6fa-4507-b341-0d35689a097d'	System	11 Sep 2020 19:13:03
User entered '11 Sep 2020 14:12'	System	11 Sep 2020 19:13:03

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '11 Sep 2020 12:00'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '12 Sep 2020 11:59'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	07 Sep 2020 13:54:23
User entered 'Day 6'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-12T12:53:40', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '6a599451-9ee0-4705-ac49-5a41d215e511'	System	12 Sep 2020 17:54:05
User entered 'None (0)'	System	12 Sep 2020 17:54:05

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-12T12:53:42', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '6a599451-9ee0-4705-ac49-5a41d215e511'	System	12 Sep 2020 17:54:05
User entered 'None (0)'	System	12 Sep 2020 17:54:05

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-12T12:53:45', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '6a599451-9ee0-4705-ac49-5a41d215e511'	System	12 Sep 2020 17:54:05
User entered 'None (0)'	System	12 Sep 2020 17:54:05

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-12T12:53:48', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '6a599451-9ee0-4705-ac49-5a41d215e511'	System	12 Sep 2020 17:54:05
User entered 'None (0)'	System	12 Sep 2020 17:54:05

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-12T12:53:51', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '6a599451-9ee0-4705-ac49-5a41d215e511'	System	12 Sep 2020 17:54:05
User entered 'None (0)'	System	12 Sep 2020 17:54:05

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-12T12:53:53', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '6a599451-9ee0-4705-ac49-5a41d215e511'	System	12 Sep 2020 17:54:05
User entered 'None (0)'	System	12 Sep 2020 17:54:05

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-12T12:54:00', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '6a599451-9ee0-4705-ac49-5a41d215e511'	System	12 Sep 2020 17:54:05
User entered 'No (N)'	System	12 Sep 2020 17:54:05

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-12T12:54:02', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '6a599451-9ee0-4705-ac49-5a41d215e511'	System	12 Sep 2020 17:54:05
User entered '12 Sep 2020 12:54'	System	12 Sep 2020 17:54:05

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '12 Sep 2020 12:00'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '13 Sep 2020 11:59'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	07 Sep 2020 13:54:23
User entered 'Day 7'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-13T13:11:58', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '76584b5f-dcf3-45b5-adda-85573110c38d'	System	13 Sep 2020 18:12:43
User entered 'None (0)'	System	13 Sep 2020 18:12:43

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-13T13:12:01', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '76584b5f-dcf3-45b5-adda-85573110c38d'	System	13 Sep 2020 18:12:43
User entered 'None (0)'	System	13 Sep 2020 18:12:43

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-13T13:12:04', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '76584b5f-dcf3-45b5-adda-85573110c38d'	System	13 Sep 2020 18:12:43
User entered 'None (0)'	System	13 Sep 2020 18:12:43

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-13T13:12:06', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '76584b5f-dcf3-45b5-adda-85573110c38d'	System	13 Sep 2020 18:12:43
User entered 'None (0)'	System	13 Sep 2020 18:12:43

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-13T13:12:09', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '76584b5f-dcf3-45b5-adda-85573110c38d'	System	13 Sep 2020 18:12:43
User entered 'None (0)'	System	13 Sep 2020 18:12:43

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-13T13:12:11', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '76584b5f-dcf3-45b5-adda-85573110c38d'	System	13 Sep 2020 18:12:43
User entered 'None (0)'	System	13 Sep 2020 18:12:43

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-13T13:12:15', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '76584b5f-dcf3-45b5-adda-85573110c38d'	System	13 Sep 2020 18:12:43
User entered 'No (N)'	System	13 Sep 2020 18:12:43

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-09-13T13:12:17', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '76584b5f-dcf3-45b5-adda-85573110c38d'	System	13 Sep 2020 18:12:43
User entered '13 Sep 2020 13:12'	System	13 Sep 2020 18:12:43

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '13 Sep 2020 12:00'	System	07 Sep 2020 13:54:23

US3552005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
User entered '14 Sep 2020 11:59'	System	07 Sep 2020 13:54:23

US3552005

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	15 Sep 2020 18:24:48

US3552005

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '15 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Sep 2020 18:24:48

US3552005

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	15 Sep 2020 18:24:48

US3552005

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered empty.	Stanley Dublin (b) (4) (b) (4)	15 Sep 2020 18:24:48

US3552005

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Heather Douds (b) (4)	24 Sep 2020 19:54:02
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Heather Douds (b) (4)	24 Sep 2020 19:53:58
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Stanley Doublin (b) (4)	23 Sep 2020 17:52:12
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Stanley Doublin (b) (4)	23 Sep 2020 17:52:05
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Stanley Doublin (b) (4)	22 Sep 2020 19:13:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Stanley Doublin (b) (4)	22 Sep 2020 19:12:52
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Stanley Doublin (b) (4)	22 Sep 2020 17:53:33
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Stanley Doublin (b) (4)	22 Sep 2020 17:53:14
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Stanley Doublin (b) (4)	22 Sep 2020 17:52:08
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Stanley Doublin (b) (4)	22 Sep 2020 17:52:02
User entered 'Yes (Y)'	(b) (4)	
	Stanley Doublin (b) (4)	22 Sep 2020 17:51:34

US3552005

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User entered 'I'	System	24 Sep 2020 19:54:02
User entered empty.	System	24 Sep 2020 19:53:58
User entered 'I'	System	23 Sep 2020 17:52:12
User entered empty.	System	23 Sep 2020 17:52:05
User entered 'I'	System	22 Sep 2020 19:13:31
User entered empty.	System	22 Sep 2020 19:12:52
User entered 'I'	System	22 Sep 2020 17:53:33
User entered empty.	System	22 Sep 2020 17:53:14
User entered 'I'	System	22 Sep 2020 17:52:08
User entered empty.	System	22 Sep 2020 17:52:02
User entered 'I'	System	22 Sep 2020 17:51:34

US3552005

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	24 Sep 2020 14:22:16

US3552005

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '22 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Sep 2020 14:22:16

US3552005

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	24 Sep 2020 14:22:16

US3552005

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered empty.	Stanley Dublin (b) (4) (b) (4)	24 Sep 2020 14:22:16

US3552005

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Sep 2020 18:11:50

US3552005

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User entered 'l'	System	29 Sep 2020 18:11:50

US3552005

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	29 Sep 2020 18:11:59

US3552005

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '29 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Sep 2020 18:11:59

US3552005

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	29 Sep 2020 18:11:59

US3552005

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered empty.	Stanley Dublin (b) (4) (b) (4)	29 Sep 2020 18:11:59

US3552005

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 15:35:29

US3552005

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User entered 'l'	System	02 Oct 2020 15:35:29

US3552005

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:04:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 15:36:33

US3552005

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered '2 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 15:36:33

US3552005

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Clinic (Clinic)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 15:36:33

US3552005

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:04:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered 'VISIT3'	System	02 Oct 2020 15:36:33

US3552005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 15:36:54

US3552005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered empty.	Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 15:36:54

US3552005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered empty.	Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 15:36:54

US3552005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered empty.	System	02 Oct 2020 15:36:54

US3552005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered empty.	Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 15:36:54

US3552005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered empty.	Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 15:36:54

US3552005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered empty.	Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 15:36:54

US3552005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered empty.	Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 15:36:54

US3552005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered empty.	System	02 Oct 2020 15:36:54

US3552005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered empty.	Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 15:36:54

US3552005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered empty.	System	02 Oct 2020 15:36:54

US3552005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered empty.	Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 15:36:54

US3552005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered empty.	System	02 Oct 2020 15:36:54

US3552005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered empty.	Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 15:36:54

US3552005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered empty.	System	02 Oct 2020 15:36:54

US3552005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46

US3552005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46

US3552005

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:04:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 15:37:00

US3552005

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:04:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 15:37:00

US3552005

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 15:37:12

US3552005

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '2 Oct 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 15:37:12

US3552005

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered '08:56'	Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 15:37:12

US3552005

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered '2 Oct 2020 08:56'	System	02 Oct 2020 15:37:12

US3552005

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Jan 2021 15:41:18

US3552005

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:46
User entered 'l'	System	04 Jan 2021 15:41:18

US3552005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered 'Day 64'	System	11 Aug 2020 16:46:41

US3552005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-10-11T07:35:33', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'f27fe708-270d-43cb-a976-7ff87269f1e3'	System	11 Oct 2020 12:35:46
User entered 'No (N)'	System	11 Oct 2020 12:35:46

US3552005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-10-11T07:35:40', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'f27fe708-270d-43cb-a976-7ff87269f1e3'	System	11 Oct 2020 12:35:46
User entered 'No (N)'	System	11 Oct 2020 12:35:46

US3552005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-10-11T07:35:44', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'f27fe708-270d-43cb-a976-7ff87269f1e3' User entered '11 Oct 2020 07:35:44'	System	11 Oct 2020 12:35:46
	System	11 Oct 2020 12:35:46

US3552005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered '11 Oct 2020 00:01'	System	11 Aug 2020 16:46:41

US3552005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered '15 Oct 2020 23:59'	System	11 Aug 2020 16:46:41

US3552005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered 'Day 71'	System	11 Aug 2020 16:46:41

US3552005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-10-21T14:18:47', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '7d306087-cae5-4c54-a69d-91fed3e8ca36'	System	21 Oct 2020 19:19:04
User entered 'No (N)'	System	21 Oct 2020 19:19:04

US3552005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-10-21T14:18:54', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '7d306087-cae5-4c54-a69d-91fed3e8ca36'	System	21 Oct 2020 19:19:04
User entered 'No (N)'	System	21 Oct 2020 19:19:04

US3552005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-10-21T14:18:57', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '7d306087-cae5-4c54-a69d-91fed3e8ca36'	System	21 Oct 2020 19:19:04
User entered '21 Oct 2020 14:18:57'	System	21 Oct 2020 19:19:04

US3552005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered '18 Oct 2020 00:01'	System	11 Aug 2020 16:46:41

US3552005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered '22 Oct 2020 23:59'	System	11 Aug 2020 16:46:41

US3552005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered 'Day 78'	System	11 Aug 2020 16:46:41

US3552005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-10-26T16:41:10', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '48968d52-6414-4990-b610-282e21fbf156'	System	26 Oct 2020 21:41:25
User entered 'No (N)'	System	26 Oct 2020 21:41:25

US3552005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-10-26T16:41:19', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '48968d52-6414-4990-b610-282e21fbf156'	System	26 Oct 2020 21:41:25
User entered 'No (N)'	System	26 Oct 2020 21:41:25

US3552005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-10-26T16:41:22', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '48968d52-6414-4990-b610-282e21fbf156'	System	26 Oct 2020 21:41:25
User entered '26 Oct 2020 16:41:22'	System	26 Oct 2020 21:41:25

US3552005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered '25 Oct 2020 00:01'	System	11 Aug 2020 16:46:41

US3552005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered '29 Oct 2020 23:59'	System	11 Aug 2020 16:46:41

US3552005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered 'Day 92'	System	11 Aug 2020 16:46:41

US3552005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-11-09T08:40:20', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '3d7f0a14-8a6d-4794-b72e-7b46d959db1f'	System	09 Nov 2020 14:40:39
User entered 'No (N)'	System	09 Nov 2020 14:40:39

US3552005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-11-09T08:40:29', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '3d7f0a14-8a6d-4794-b72e-7b46d959db1f'	System	09 Nov 2020 14:40:39
User entered 'No (N)'	System	09 Nov 2020 14:40:39

US3552005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-11-09T08:40:32', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '3d7f0a14-8a6d-4794-b72e-7b46d959db1f' User entered '09 Nov 2020 08:40:32'	System	09 Nov 2020 14:40:39
	System	09 Nov 2020 14:40:39

US3552005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered '08 Nov 2020 00:01'	System	11 Aug 2020 16:46:41

US3552005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered '12 Nov 2020 23:59'	System	11 Aug 2020 16:46:41

US3552005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered 'Day 99'	System	11 Aug 2020 16:46:41

US3552005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-11-16T08:30:40', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '284a6d94-2249-425b-8a90-626d5f25b781'	System	16 Nov 2020 14:30:51
User entered 'No (N)'	System	16 Nov 2020 14:30:51

US3552005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-11-16T08:30:46', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '284a6d94-2249-425b-8a90-626d5f25b781'	System	16 Nov 2020 14:30:51
User entered 'No (N)'	System	16 Nov 2020 14:30:51

US3552005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-11-16T08:30:49', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '284a6d94-2249-425b-8a90-626d5f25b781'	System	16 Nov 2020 14:30:51
User entered '16 Nov 2020 08:30:49'	System	16 Nov 2020 14:30:51

US3552005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered '15 Nov 2020 00:01'	System	11 Aug 2020 16:46:41

US3552005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:20
Data entry locked.	System	11 Aug 2020 16:46:41
User entered '19 Nov 2020 23:59'	System	11 Aug 2020 16:46:41

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[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 (4cb570e94ecfc767)', Time: '2020-11-20T16:23:12', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'b94b1ede-8e15-4d15-a5b7-8bf92b456a83'	System	20 Nov 2020 22:23:32
User entered 'No (N)'	System	20 Nov 2020 22:23:32

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Have you been exposed to someone with 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 (4cb570e94ecfc767)', Time: '2020-11-20T16:23:24', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'b94b1ede-8e15-4d15-a5b7-8bf92b456a83'	System	20 Nov 2020 22:23:32
User entered 'No (N)'	System	20 Nov 2020 22:23:32

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-11-20T16:23:27', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'b94b1ede-8e15-4d15-a5b7-8bf92b456a83'	System	20 Nov 2020 22:23:32
User entered '20 Nov 2020 16:23:27'	System	20 Nov 2020 22:23:32

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[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 (4cb570e94ecfc767)', Time: '2020-11-26T20:26:39', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '1cddc437-7b19-4c15-8af9-7ceb8197f9b0'	System	27 Nov 2020 02:26:56
User entered 'No (N)'	System	27 Nov 2020 02:26:56

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

Have you been exposed to someone with 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 (4cb570e94ecfc767)', Time: '2020-11-26T20:26:47', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '1cddc437-7b19-4c15-8af9-7ceb8197f9b0'	System	27 Nov 2020 02:26:56
User entered 'No (N)'	System	27 Nov 2020 02:26:56

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-11-26T20:26:51', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '1cddc437-7b19-4c15-8af9-7ceb8197f9b0'	System	27 Nov 2020 02:26:56
User entered '26 Nov 2020 20:26:51'	System	27 Nov 2020 02:26:56

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[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 (4cb570e94ecfc767)', Time: '2020-12-06T20:52:28', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '70d7ec47-037e-4ef7-a6aa-861e940f3fc1'	System	07 Dec 2020 02:53:44
User entered 'No (N)'	System	07 Dec 2020 02:53:44

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Have you been exposed to someone with 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 (4cb570e94ecfc767)', Time: '2020-12-06T20:52:41', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '70d7ec47-037e-4ef7-a6aa-861e940f3fc1'	System	07 Dec 2020 02:53:44
User entered 'No (N)'	System	07 Dec 2020 02:53:44

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-12-06T20:52:44', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '70d7ec47-037e-4ef7-a6aa-861e940f3fc1' User entered '06 Dec 2020 20:52:44'	System	07 Dec 2020 02:53:44

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[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 (4cb570e94ecfc767)', Time: '2020-12-11T12:49:18', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ef545d2f-de39-4c14-98da-5aec8c1132cf'	System	11 Dec 2020 18:49:33
User entered 'No (N)'	System	11 Dec 2020 18:49:33

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Have you been exposed to someone with 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 (4cb570e94ecfc767)', Time: '2020-12-11T12:49:24', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ef545d2f-de39-4c14-98da-5aec8c1132cf'	System	11 Dec 2020 18:49:33
User entered 'No (N)'	System	11 Dec 2020 18:49:33

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-12-11T12:49:27', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ef545d2f-de39-4c14-98da-5aec8c1132cf' User entered '11 Dec 2020 12:49:27'	System	11 Dec 2020 18:49:33
	System	11 Dec 2020 18:49:33

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[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 (4cb570e94ecfc767)', Time: '2020-12-17T14:12:23', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'c4d927b4-5594-4345-ba98-4567dfd20e42'	System	17 Dec 2020 20:12:37
User entered 'No (N)'	System	17 Dec 2020 20:12:37

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Have you been exposed to someone with 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 (4cb570e94ecfc767)', Time: '2020-12-17T14:12:31', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'c4d927b4-5594-4345-ba98-4567dfd20e42'	System	17 Dec 2020 20:12:37
User entered 'No (N)'	System	17 Dec 2020 20:12:37

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-12-17T14:12:34', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'c4d927b4-5594-4345-ba98-4567dfd20e42'	System	17 Dec 2020 20:12:37
User entered '17 Dec 2020 14:12:34'	System	17 Dec 2020 20:12:37

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[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 (4cb570e94ecfc767)', Time: '2020-12-27T09:48:24', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '8369033c-b55c-48e9-8a57-43219bc49ced'	System	27 Dec 2020 15:48:38
User entered 'No (N)'	System	27 Dec 2020 15:48:38

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Have you been exposed to someone with 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 (4cb570e94ecfc767)', Time: '2020-12-27T09:48:32', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '8369033c-b55c-48e9-8a57-43219bc49ced'	System	27 Dec 2020 15:48:38
User entered 'No (N)'	System	27 Dec 2020 15:48:38

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2020-12-27T09:48:35', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '8369033c-b55c-48e9-8a57-43219bc49ced'	System	27 Dec 2020 15:48:38
User entered '27 Dec 2020 09:48:35'	System	27 Dec 2020 15:48:38

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[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 (4cb570e94ecfc767)', Time: '2021-01-04T09:19:46', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '7c83f329-06bf-4707-96d1-f2838f62f92e'	System	04 Jan 2021 15:19:59
User entered 'No (N)'	System	04 Jan 2021 15:19:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

Have you been exposed to someone with 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 (4cb570e94ecfc767)', Time: '2021-01-04T09:19:50', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '7c83f329-06bf-4707-96d1-f2838f62f92e'	System	04 Jan 2021 15:19:59
User entered 'No (N)'	System	04 Jan 2021 15:19:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2021-01-04T09:19:53', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '7c83f329-06bf-4707-96d1-f2838f62f92e' User entered '04 Jan 2021 09:19:53'	System	04 Jan 2021 15:19:59
	System	04 Jan 2021 15:19:59

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[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 (4cb570e94ecfc767)', Time: '2021-01-07T21:13:43', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'd516ef09-936c-42d7-aeb1-e1ab35d02691'	System	08 Jan 2021 03:13:53
User entered 'No (N)'	System	08 Jan 2021 03:13:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

Have you been exposed to someone with 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 (4cb570e94ecfc767)', Time: '2021-01-07T21:13:49', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'd516ef09-936c-42d7-aeb1-e1ab35d02691'	System	08 Jan 2021 03:13:53
User entered 'No (N)'	System	08 Jan 2021 03:13:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2021-01-07T21:13:51', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'd516ef09-936c-42d7-aeb1-e1ab35d02691'	System	08 Jan 2021 03:13:53
User entered '07 Jan 2021 21:13:51'	System	08 Jan 2021 03:13:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[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 (4cb570e94ecfc767)', Time: '2021-01-14T20:44:09', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ee1328b4-a37c-4f25-b586-6d3447ae518f'	System	15 Jan 2021 02:44:23
User entered 'No (N)'	System	15 Jan 2021 02:44:23

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

Have you been exposed to someone with 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 (4cb570e94ecfc767)', Time: '2021-01-14T20:44:17', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ee1328b4-a37c-4f25-b586-6d3447ae518f'	System	15 Jan 2021 02:44:23
User entered 'No (N)'	System	15 Jan 2021 02:44:23

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2021-01-14T20:44:20', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'ee1328b4-a37c-4f25-b586-6d3447ae518f' User entered '14 Jan 2021 20:44:20'	System	15 Jan 2021 02:44:23

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[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 (4cb570e94ecfc767)', Time: '2021-01-21T20:42:02', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '98031cc1-37e9-4522-81d2-1c174bf94f2a'	System	22 Jan 2021 02:42:22
User entered 'No (N)'	System	22 Jan 2021 02:42:22

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Have you been exposed to someone with 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 (4cb570e94ecfc767)', Time: '2021-01-21T20:42:12', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '98031cc1-37e9-4522-81d2-1c174bf94f2a'	System	22 Jan 2021 02:42:22
User entered 'No (N)'	System	22 Jan 2021 02:42:22

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2021-01-21T20:42:16', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '98031cc1-37e9-4522-81d2-1c174bf94f2a'	System	22 Jan 2021 02:42:22
User entered '21 Jan 2021 20:42:16'	System	22 Jan 2021 02:42:22

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[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 (4cb570e94ecfc767)', Time: '2021-01-28T20:48:37', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'c4364f62-c522-42db-b440-34b6ecd936d7'	System	29 Jan 2021 02:48:51
User entered 'No (N)'	System	29 Jan 2021 02:48:51

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Have you been exposed to someone with 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 (4cb570e94ecfc767)', Time: '2021-01-28T20:48:43', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'c4364f62-c522-42db-b440-34b6ecd936d7'	System	29 Jan 2021 02:48:51
User entered 'No (N)'	System	29 Jan 2021 02:48:51

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2021-01-28T20:48:48', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'c4364f62-c522-42db-b440-34b6ecd936d7' User entered '28 Jan 2021 20:48:48'	System	29 Jan 2021 02:48:51

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[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 (4cb570e94ecfc767)', Time: '2021-02-04T07:57:16', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '8be3f326-b37e-4dba-9230-b473e8154cc6'	System	04 Feb 2021 13:57:25
User entered 'No (N)'	System	04 Feb 2021 13:57:25

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Have you been exposed to someone with 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 (4cb570e94ecfc767)', Time: '2021-02-04T07:57:20', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '8be3f326-b37e-4dba-9230-b473e8154cc6'	System	04 Feb 2021 13:57:25
User entered 'No (N)'	System	04 Feb 2021 13:57:25

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2021-02-04T07:57:23', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '8be3f326-b37e-4dba-9230-b473e8154cc6'	System	04 Feb 2021 13:57:25
User entered '04 Feb 2021 07:57:23'	System	04 Feb 2021 13:57:25

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[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 (4cb570e94ecfc767)', Time: '2021-02-11T15:23:19', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '545e1bd1-da61-4dd2-88c1-d7e798a7921d'	System	11 Feb 2021 21:23:38
User entered 'No (N)'	System	11 Feb 2021 21:23:38

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

Have you been exposed to someone with 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 (4cb570e94ecfc767)', Time: '2021-02-11T15:23:25', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '545e1bd1-da61-4dd2-88c1-d7e798a7921d'	System	11 Feb 2021 21:23:38
User entered 'No (N)'	System	11 Feb 2021 21:23:38

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2021-02-11T15:23:28', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '545e1bd1-da61-4dd2-88c1-d7e798a7921d'	System	11 Feb 2021 21:23:38
User entered '11 Feb 2021 15:23:28'	System	11 Feb 2021 21:23:38

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[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 (4cb570e94ecfc767)', Time: '2021-02-18T13:59:13', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '5e741dc6-3fe3-4f54-96f1-2d6d6b332e3a'	System	18 Feb 2021 19:59:23
User entered 'No (N)'	System	18 Feb 2021 19:59:23

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Have you been exposed to someone with 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 (4cb570e94ecfc767)', Time: '2021-02-18T13:59:15', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '5e741dc6-3fe3-4f54-96f1-2d6d6b332e3a'	System	18 Feb 2021 19:59:23
User entered 'No (N)'	System	18 Feb 2021 19:59:23

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2021-02-18T13:59:19', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '5e741dc6-3fe3-4f54-96f1-2d6d6b332e3a'	System	18 Feb 2021 19:59:23
User entered '18 Feb 2021 13:59:19'	System	18 Feb 2021 19:59:23

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[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 (4cb570e94ecfc767)', Time: '2021-02-25T18:44:27', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'b702be0c-15fe-4add-874c-5d664a8eec91'	System	26 Feb 2021 05:17:14
User entered 'Yes (Y)'	System	26 Feb 2021 05:17:14

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

Have you been exposed to someone with 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 (4cb570e94ecfc767)', Time: '2021-02-25T18:44:32', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'b702be0c-15fe-4add-874c-5d664a8eec91'	System	26 Feb 2021 05:17:14
User entered 'No (N)'	System	26 Feb 2021 05:17:14

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[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 (4cb570e94ecfc767)', Time: '2021-02-25T18:44:38', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'b702be0c-15fe-4add-874c-5d664a8eec91'	System	26 Feb 2021 05:17:14
User entered 'No (N)'	System	26 Feb 2021 05:17:14

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[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 (4cb570e94ecfc767)', Time: '2021-02-25T18:44:58', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'b702be0c-15fe-4add-874c-5d664a8eec91'	System	26 Feb 2021 05:17:14
User entered 'Yes (Y)'	System	26 Feb 2021 05:17:14

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Please 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 (4cb570e94ecfc767)', Time: '2021-02-25T18:45:18', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'b702be0c-15fe-4add-874c-5d664a8eec91'	System	26 Feb 2021 05:17:14
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Feb 2021 05:17:14

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2021-02-25T18:45:24', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'b702be0c-15fe-4add-874c-5d664a8eec91'	System	26 Feb 2021 05:17:14
User entered '25 Feb 2021 18:45:24'	System	26 Feb 2021 05:17:14

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[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 (4cb570e94ecfc767)', Time: '2021-03-08T19:10:38', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '91892814-8ec8-443f-99fa-8a87843bb762'	System	09 Mar 2021 01:10:51
User entered 'No (N)'	System	09 Mar 2021 01:10:51

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Have you been exposed to someone with 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 (4cb570e94ecfc767)', Time: '2021-03-08T19:10:42', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '91892814-8ec8-443f-99fa-8a87843bb762'	System	09 Mar 2021 01:10:51
User entered 'No (N)'	System	09 Mar 2021 01:10:51

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2021-03-08T19:10:46', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '91892814-8ec8-443f-99fa-8a87843bb762'	System	09 Mar 2021 01:10:51
User entered '08 Mar 2021 19:10:46'	System	09 Mar 2021 01:10:51

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[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 (4cb570e94ecfc767)', Time: '2021-03-13T08:31:05', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'a8564166-df67-46b2-8bf4-570fd25124c8'	System	13 Mar 2021 14:31:18
User entered 'No (N)'	System	13 Mar 2021 14:31:18

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Have you been exposed to someone with 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 (4cb570e94ecfc767)', Time: '2021-03-13T08:31:11', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'a8564166-df67-46b2-8bf4-570fd25124c8'	System	13 Mar 2021 14:31:18
User entered 'No (N)'	System	13 Mar 2021 14:31:18

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2021-03-13T08:31:14', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'a8564166-df67-46b2-8bf4-570fd25124c8'	System	13 Mar 2021 14:31:18
User entered '13 Mar 2021 08:31:14'	System	13 Mar 2021 14:31:18

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[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 (4cb570e94ecfc767)', Time: '2021-03-20T01:38:16', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '60844895-0aa0-4cb3-b84f-470d0523d646'	System	20 Mar 2021 06:38:35
User entered 'No (N)'	System	20 Mar 2021 06:38:35

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Have you been exposed to someone with 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 (4cb570e94ecfc767)', Time: '2021-03-20T01:38:27', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '60844895-0aa0-4cb3-b84f-470d0523d646'	System	20 Mar 2021 06:38:35
User entered 'No (N)'	System	20 Mar 2021 06:38:35

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2021-03-20T01:38:30', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '60844895-0aa0-4cb3-b84f-470d0523d646'	System	20 Mar 2021 06:38:35
User entered '20 Mar 2021 01:38:30'	System	20 Mar 2021 06:38:35

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[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 (4cb570e94ecfc767)', Time: '2021-03-25T06:57:34', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'b891610d-811b-4e09-b21b-ed081a1b300e'	System	25 Mar 2021 11:57:45
User entered 'No (N)'	System	25 Mar 2021 11:57:45

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Have you been exposed to someone with 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 (4cb570e94ecfc767)', Time: '2021-03-25T06:57:40', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'b891610d-811b-4e09-b21b-ed081a1b300e'	System	25 Mar 2021 11:57:45
User entered 'No (N)'	System	25 Mar 2021 11:57:45

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2021-03-25T06:57:43', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'b891610d-811b-4e09-b21b-ed081a1b300e' User entered '25 Mar 2021 06:57:43'	System	25 Mar 2021 11:57:45

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[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 (4cb570e94ecfc767)', Time: '2021-04-04T20:47:18', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'c13d75f3-3104-4457-a7e7-e320d12580ea'	System	05 Apr 2021 01:47:27
User entered 'No (N)'	System	05 Apr 2021 01:47:27

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Have you been exposed to someone with 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 (4cb570e94ecfc767)', Time: '2021-04-04T20:47:22', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'c13d75f3-3104-4457-a7e7-e320d12580ea'	System	05 Apr 2021 01:47:27
User entered 'No (N)'	System	05 Apr 2021 01:47:27

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2021-04-04T20:47:25', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: 'c13d75f3-3104-4457-a7e7-e320d12580ea' User entered '04 Apr 2021 20:47:25'	System	05 Apr 2021 01:47:27

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[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 (4cb570e94ecfc767)', Time: '2021-04-08T12:55:56', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '5da9685c-c8b6-4b8d-8464-228178b947e6'	System	08 Apr 2021 17:56:03
User entered 'No (N)'	System	08 Apr 2021 17:56:03

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Have you been exposed to someone with 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 (4cb570e94ecfc767)', Time: '2021-04-08T12:55:58', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '5da9685c-c8b6-4b8d-8464-228178b947e6'	System	08 Apr 2021 17:56:03
User entered 'No (N)'	System	08 Apr 2021 17:56:03

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2021-04-08T12:56:01', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '5da9685c-c8b6-4b8d-8464-228178b947e6'	System	08 Apr 2021 17:56:03
User entered '08 Apr 2021 12:56:01'	System	08 Apr 2021 17:56:03

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[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 (4cb570e94ecfc767)', Time: '2021-04-16T20:12:30', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '4dd2070b-9bed-41e0-9b65-cf61c5d1e6ff'	System	17 Apr 2021 01:13:40
User entered 'No (N)'	System	17 Apr 2021 01:13:40

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Have you been exposed to someone with 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 (4cb570e94ecfc767)', Time: '2021-04-16T20:12:32', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '4dd2070b-9bed-41e0-9b65-cf61c5d1e6ff'	System	17 Apr 2021 01:13:40
User entered 'No (N)'	System	17 Apr 2021 01:13:40

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2021-04-16T20:12:35', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '4dd2070b-9bed-41e0-9b65-cf61c5d1e6ff' User entered '16 Apr 2021 20:12:35'	System	17 Apr 2021 01:13:40
	System	17 Apr 2021 01:13:40

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[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 (4cb570e94ecfc767)', Time: '2021-04-22T21:28:28', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '56acb7e6-d2e9-43e5-98ed-e46d8a411fa5'	System	23 Apr 2021 02:28:40
User entered 'No (N)'	System	23 Apr 2021 02:28:40

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

Have you been exposed to someone with 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 (4cb570e94ecfc767)', Time: '2021-04-22T21:28:35', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '56acb7e6-d2e9-43e5-98ed-e46d8a411fa5'	System	23 Apr 2021 02:28:40
User entered 'No (N)'	System	23 Apr 2021 02:28:40

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2021-04-22T21:28:37', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '56acb7e6-d2e9-43e5-98ed-e46d8a411fa5'	System	23 Apr 2021 02:28:40
User entered '22 Apr 2021 21:28:37'	System	23 Apr 2021 02:28:40

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[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 (4cb570e94ecfc767)', Time: '2021-04-30T20:40:41', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '3d7e98c0-7cbc-4a65-992e-c49e91b8cfef'	System	01 May 2021 01:40:56
User entered 'No (N)'	System	01 May 2021 01:40:56

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

Have you been exposed to someone with 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 (4cb570e94ecfc767)', Time: '2021-04-30T20:40:50', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '3d7e98c0-7cbc-4a65-992e-c49e91b8cfef'	System	01 May 2021 01:40:56
User entered 'No (N)'	System	01 May 2021 01:40:56

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2021-04-30T20:40:52', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '3d7e98c0-7cbc-4a65-992e-c49e91b8cfef'	System	01 May 2021 01:40:56
User entered '30 Apr 2021 20:40:52'	System	01 May 2021 01:40:56

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 03:49:53

US3552005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:53
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 03:49:53

US3552005

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:04:59

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:56:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2021-03-08T19:10:28', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '41698363-b518-44eb-8c73-c1de88838b96'	System	09 Mar 2021 01:10:38
User entered 'No (N)'	System	09 Mar 2021 01:10:38

US3552005

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:04:59

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:56:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb570e94ecfc767)', Time: '2021-03-08T19:10:30', User OID: 'PatientReportedOutcome (US3552005)', ODM File OID: '41698363-b518-44eb-8c73-c1de88838b96'	System	09 Mar 2021 01:10:38
User entered '08 Mar 2021 19:10:30'	System	09 Mar 2021 01:10:38

US3552005

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	04 Jan 2021 15:41:26

US3552005

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Stanley Dublin (b) (4)	04 Jan 2021 15:41:26

US3552005

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Jan 2021 15:41:26

US3552005

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered empty.	Stanley Dublin (b) (4) (b) (4)	04 Jan 2021 15:41:26

US3552005

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Jan 2021 15:41:46

US3552005

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:35
User entered 'l'	System	04 Jan 2021 15:41:46

US3552005

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Jan 2021 15:41:56

US3552005

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Jan 2021 15:41:56

US3552005

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Jan 2021 15:41:56

US3552005

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Jan 2021 15:41:56

US3552005

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Jan 2021 15:42:03

US3552005

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User entered 'l'	System	04 Jan 2021 15:42:03

US3552005

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Jan 2021 15:42:30

US3552005

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '04 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Jan 2021 15:42:30

US3552005

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Jan 2021 15:42:30

US3552005

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Jan 2021 15:42:30

US3552005

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 15:23:36

US3552005

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User entered 'l'	System	01 Feb 2021 15:23:36

US3552005

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 15:23:48

US3552005

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '01 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 15:23:48

US3552005

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 15:23:48

US3552005

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 15:23:48

US3552005

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	11 Feb 2021 20:50:54

US3552005

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User entered 'l'	System	11 Feb 2021 20:50:54

US3552005

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:04:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:06:55
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:16:21

US3552005

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:06:55
User entered '22 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:16:21

US3552005

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:06:55
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:16:21

US3552005

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:04:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User entered 'VISIT4'	System	22 Feb 2021 19:16:21

US3552005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:29
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 20:01:52
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 20:01:52
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:16:58
	(b) (4)	
User entered 'No (N)'	Cassandra Zehenny (b) (4)	29 Mar 2021 16:33:33
	(b) (4)	

US3552005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:29
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 20:01:52
	(b) (4)	
User entered '22 Feb 2021' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	30 Mar 2021 20:01:52
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:16:58
	(b) (4)	
User entered empty.	Cassandra Zehenny (b) (4)	29 Mar 2021 16:33:33
	(b) (4)	

US3552005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:29
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 20:01:52
User entered '09:52' reason for change: Per Query Resolution	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 20:01:52
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:16:58
	(b) (4)	
User entered empty.	Cassandra Zehenny (b) (4)	29 Mar 2021 16:33:33
	(b) (4)	

US3552005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User entered '22 Feb 2021 09:52'	System	30 Mar 2021 20:01:52
User entered empty.	System	29 Mar 2021 16:33:33

US3552005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:29
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 20:01:52
User entered '98.1' F reason for change: Per Query Resolution	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 20:01:52
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:16:58
	(b) (4)	
User entered empty.	Cassandra Zehenny (b) (4)	29 Mar 2021 16:33:33
	(b) (4)	

US3552005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:29
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 20:01:52
User entered 'Oral (Oral)' reason for change: Per	(b) (4)	
Query Resolution	Cassandra Zehenny (b) (4)	30 Mar 2021 20:01:52
User signature succeeded.	(b) (4)	
	sharon frey (b) (4)	30 Mar 2021 16:16:58
User entered empty.	(b) (4)	
	Cassandra Zehenny (b) (4)	29 Mar 2021 16:33:33
	(b) (4)	

US3552005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:16:58
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	29 Mar 2021 16:33:33

US3552005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:29
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 20:01:52
	(b) (4)	
User entered '75' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	30 Mar 2021 20:01:52
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:16:58
	(b) (4)	
User entered empty.	Cassandra Zehenny (b) (4)	29 Mar 2021 16:33:33
	(b) (4)	

US3552005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User entered 'bpm'	System	30 Mar 2021 20:01:52
User entered empty.	System	29 Mar 2021 16:33:33

US3552005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:29
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 20:01:52
	(b) (4)	
User entered '17' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	30 Mar 2021 20:01:52
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:16:58
	(b) (4)	
User entered empty.	Cassandra Zehenny (b) (4)	29 Mar 2021 16:33:33
	(b) (4)	

US3552005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User entered 'breaths/min'	System	30 Mar 2021 20:01:52
User entered empty.	System	29 Mar 2021 16:33:33

US3552005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:29
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 20:01:52
	(b) (4)	
User entered '96' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	30 Mar 2021 20:01:52
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:16:58
	(b) (4)	
User entered empty.	Cassandra Zehenny (b) (4)	29 Mar 2021 16:33:33
	(b) (4)	

US3552005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User entered 'mmHg'	System	30 Mar 2021 20:01:52
User entered empty.	System	29 Mar 2021 16:33:33

US3552005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:29
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 20:01:52
	(b) (4)	
User entered '60' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	30 Mar 2021 20:01:52
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:16:58
	(b) (4)	
User entered empty.	Cassandra Zehenny (b) (4)	29 Mar 2021 16:33:33
	(b) (4)	

US3552005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User entered 'mmHg'	System	30 Mar 2021 20:01:52
User entered empty.	System	29 Mar 2021 16:33:33

US3552005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29

US3552005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29

US3552005

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:04:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:29
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 20:02:05
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 20:02:05
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:16:58
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 14:29:59
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 14:29:59
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:06:55
User entered 'Yes (Y)'	(b) (4)	
	Stanley Dublin (b) (4)	22 Feb 2021 19:16:26
	(b) (4)	

US3552005

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:04:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:29
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 20:02:05
	(b) (4)	
User entered '22 Feb 2021' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	30 Mar 2021 20:02:05
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:16:58
	(b) (4)	
Signature has been broken.	Cassandra Zehenny (b) (4)	30 Mar 2021 14:29:59
	(b) (4)	
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4)	30 Mar 2021 14:29:59
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:06:55
	(b) (4)	
User entered '22 Feb 2021'	Stanley Dublin (b) (4)	22 Feb 2021 19:16:26
	(b) (4)	

US3552005

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:48:52
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 17:47:32

US3552005

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:48:52
User entered '22 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 17:47:32

US3552005

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:48:52
User entered '10:27'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 17:47:32

US3552005

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User entered '22 Feb 2021 10:27'	System	01 Mar 2021 17:47:32

US3552005

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:06:55
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:16:31

US3552005

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:29
User entered 'I'	System	22 Feb 2021 19:16:31

US3552005

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:15
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:26:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Apr 2021 08:52:47
User entered 'Yes (Y)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	06 Apr 2021 17:56:18
Query 'Data is required. Please complete.' answered with 'data entry error' (Site from System).	Stanley Dublin (b) (4)	06 Apr 2021 17:42:24
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Apr 2021 17:42:17
User entered empty; reason for change Data Entry Error	Stanley Dublin (b) (4)	06 Apr 2021 17:42:17
User entered 'Yes (Y)'	Stanley Dublin (b) (4)	06 Apr 2021 17:37:22

US3552005

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:15
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:26:04
User entered '06 Apr 2021' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	06 Apr 2021 17:56:18
User entered empty; reason for change Data Entry Error	(b) (4)	
	Stanley Dublin (b) (4)	06 Apr 2021 17:42:17
	(b) (4)	
User entered '6 Apr 2021'	Stanley Dublin (b) (4)	06 Apr 2021 17:37:22
	(b) (4)	

US3552005

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:15
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:26:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	06 Apr 2021 17:56:18
User entered empty; reason for change Data Entry Error	(b) (4)	
	Stanley Doublin (b) (4)	06 Apr 2021 17:42:17
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Stanley Doublin (b) (4)	06 Apr 2021 17:37:22
	(b) (4)	

US3552005

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:15
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:26:04
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	06 Apr 2021 17:37:22

US3552005

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:15
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:26:04
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	06 Apr 2021 17:37:52

US3552005

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:15
User entered 'l'	System	06 Apr 2021 17:37:52

US3552005

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

Form: Visit Date

Generated On: 10 Jun 2021 08:04:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4)	27 Jan 2021 20:21:04

US3552005

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

Form: Visit Date

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '27 Jan 2021'	(b) (4) Heather Douds (b) (4)	27 Jan 2021 20:21:04

US3552005

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

Form: Visit Date

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Clinic (Clinic)'	(b) (4) Heather Douds (b) (4) (b) (4)	27 Jan 2021 20:21:04

US3552005

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

Form: Visit Date

Generated On: 10 Jun 2021 08:04:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered 'UNBLND_DECIDE'	System	27 Jan 2021 20:21:04

US3552005

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

Form: Unblinding

Generated On: 10 Jun 2021 08:04:59

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '27 Jan 2021'	(b) (4) Heather Douds (b) (4)	27 Jan 2021 20:21:24

US3552005

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

Form: Unblinding

Generated On: 10 Jun 2021 08:04:59

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:33:58

US3552005

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

Form: Unblinding

Generated On: 10 Jun 2021 08:04:59

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	27 Jan 2021 20:21:24

US3552005

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

Form: Unblinding

Generated On: 10 Jun 2021 08:04:59

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:33:58

US3552005

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

Form: Unblinding

Generated On: 10 Jun 2021 08:04:59

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '27 Jan 2021'	(b) (4) Heather Douds (b) (4)	27 Jan 2021 20:21:24

US3552005

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

Form: Unblinding

Generated On: 10 Jun 2021 08:04:59

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Placebo (Placebo)'	(b) (4) Heather Douds (b) (4)	27 Jan 2021 20:21:24

US3552005

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

Form: Unblinding

Generated On: 10 Jun 2021 08:04:59

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Placebo (Placebo)'	(b) (4) Heather Douds (b) (4)	27 Jan 2021 20:21:24

US3552005

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

Form: Unblinding

Generated On: 10 Jun 2021 08:04:59

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Placebo (Placebo)'	(b) (4) Heather Douds (b) (4)	27 Jan 2021 20:21:24

US3552005

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

Form: Unblinding

Generated On: 10 Jun 2021 08:04:59

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	27 Jan 2021 20:21:24

US3552005

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

Form: Unblinding

Generated On: 10 Jun 2021 08:04:59

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered 'I'	System	27 Jan 2021 20:21:24

US3552005

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

Form: Unblinding

Generated On: 10 Jun 2021 08:04:59

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered 'I'	System	27 Jan 2021 20:21:24

US3552005

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:04:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
	Heather Douds (b) (4)	27 Jan 2021 20:23:34
User entered empty.	(b) (4)	
	Heather Douds (b) (4)	27 Jan 2021 20:23:22
	(b) (4)	

US3552005

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:04:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
	Heather Douds (b) (4)	27 Jan 2021 20:23:34
User entered empty.	(b) (4)	
	Heather Douds (b) (4)	27 Jan 2021 20:23:22
	(b) (4)	

US3552005

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:04:59

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered empty.	System	27 Jan 2021 20:23:22
DataPoint set to visible.	System	27 Jan 2021 20:21:24

US3552005

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:04:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
	Heather Douds (b) (4)	27 Jan 2021 20:23:34
User entered empty.	(b) (4)	
	Heather Douds (b) (4)	27 Jan 2021 20:23:22
	(b) (4)	

US3552005

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:04:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
	Heather Douds (b) (4)	27 Jan 2021 20:23:34
User entered empty.	(b) (4)	
	Heather Douds (b) (4)	27 Jan 2021 20:23:22
	(b) (4)	

US3552005

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:04:59

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered empty.	System	27 Jan 2021 20:23:22
DataPoint set to visible.	System	27 Jan 2021 20:21:24

US3552005

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User accepted default value 'Pre-Dose (PREDOSE)'	Heather Douds (b) (4) (b) (4)	27 Jan 2021 20:23:22

US3552005

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4)	27 Jan 2021 20:23:22

US3552005

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '27 Jan 2021'	(b) (4) Heather Douds (b) (4)	27 Jan 2021 20:23:22

US3552005

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '08:27'	(b) (4) Heather Douds (b) (4)	27 Jan 2021 20:23:22

US3552005

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered '27 Jan 2021 08:27'	System	27 Jan 2021 20:23:22

US3552005

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '98.7' F	(b) (4) Heather Douds (b) (4)	27 Jan 2021 20:23:22

US3552005

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'Oral (Oral)'	Heather Douds (b) (4) (b) (4)	27 Jan 2021 20:23:22

US3552005

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered empty.	Heather Douds (b) (4) (b) (4)	27 Jan 2021 20:23:22

US3552005

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '69'	(b) (4) Heather Douds (b) (4) (b) (4)	27 Jan 2021 20:23:22

US3552005

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered 'bpm'	System	27 Jan 2021 20:23:22

US3552005

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered '16'	Heather Douds (b) (4) (b) (4)	27 Jan 2021 20:23:22

US3552005

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered 'breaths/min'	System	27 Jan 2021 20:23:22

US3552005

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered '101'	Heather Douds (b) (4) (b) (4)	27 Jan 2021 20:23:22

US3552005

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered 'mmHg'	System	27 Jan 2021 20:23:22

US3552005

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered '63'	Heather Douds (b) (4) (b) (4)	27 Jan 2021 20:23:22

US3552005

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered 'mmHg'	System	27 Jan 2021 20:23:22

US3552005

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:04:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
	Heather Douds (b) (4)	27 Jan 2021 20:23:34
User entered empty.	(b) (4)	
	Heather Douds (b) (4)	27 Jan 2021 20:23:22
	(b) (4)	

US3552005

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:04:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
	Heather Douds (b) (4)	27 Jan 2021 20:23:34
User entered empty.	(b) (4)	
	Heather Douds (b) (4)	27 Jan 2021 20:23:22
	(b) (4)	

US3552005

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:04:59

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered empty.	System	27 Jan 2021 20:23:22
DataPoint set to visible.	System	27 Jan 2021 20:21:24

US3552005

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User accepted default value 'Post-Dose (POSTDOSE)'	Heather Douds (b) (4) (b) (4)	27 Jan 2021 20:23:22

US3552005

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	27 Jan 2021 20:23:22

US3552005

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '27 Jan 2021'	(b) (4) Heather Douds (b) (4)	27 Jan 2021 20:23:22

US3552005

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '09:24'	(b) (4) Heather Douds (b) (4)	27 Jan 2021 20:23:22

US3552005

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered '27 Jan 2021 09:24'	System	27 Jan 2021 20:23:22

US3552005

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered '98.5' F	Heather Douds (b) (4) (b) (4)	27 Jan 2021 20:23:22

US3552005

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Oral (Oral)'	(b) (4) Heather Douds (b) (4) (b) (4)	27 Jan 2021 20:23:22

US3552005

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered empty.	Heather Douds (b) (4) (b) (4)	27 Jan 2021 20:23:22

US3552005

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered '69'	Heather Douds (b) (4) (b) (4)	27 Jan 2021 20:23:22

US3552005

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered 'bpm'	System	27 Jan 2021 20:23:22

US3552005

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered '16'	Heather Douds (b) (4) (b) (4)	27 Jan 2021 20:23:22

US3552005

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered 'breaths/min'	System	27 Jan 2021 20:23:22

US3552005

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '107'	(b) (4) Heather Douds (b) (4)	27 Jan 2021 20:23:22

US3552005

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered 'mmHg'	System	27 Jan 2021 20:23:22

US3552005

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '66'	(b) (4) Heather Douds (b) (4) (b) (4)	27 Jan 2021 20:23:22

US3552005

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered 'mmHg'	System	27 Jan 2021 20:23:22

US3552005

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

Form: Physical Examination

Generated On: 10 Jun 2021 08:04:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	27 Jan 2021 20:23:41

US3552005

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

Form: Physical Examination

Generated On: 10 Jun 2021 08:04:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '27 Jan 2021'	(b) (4) Heather Douds (b) (4)	27 Jan 2021 20:23:41

US3552005

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

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4)	27 Jan 2021 20:24:11

US3552005

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

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	27 Jan 2021 20:24:11

US3552005

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

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Heather Douds (b) (4)	27 Jan 2021 20:24:11

US3552005

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

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered 'mRNA-1273'	System	27 Jan 2021 20:24:11
DataPoint set to visible.	System	27 Jan 2021 20:21:24

US3552005

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

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '27 Jan 2021'	(b) (4) Heather Douds (b) (4)	27 Jan 2021 20:24:11

US3552005

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

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '08:54'	(b) (4) Heather Douds (b) (4)	27 Jan 2021 20:24:11

US3552005

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

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered '27 Jan 2021 08:54'	System	27 Jan 2021 20:24:11

US3552005

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

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Left Arm (LEFT ARM)'	(b) (4) Heather Douds (b) (4) (b) (4)	27 Jan 2021 20:24:11

US3552005

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

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered 'ONCE'	System	27 Jan 2021 20:24:11

US3552005

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

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered 'INTRAMUSCULAR'	System	27 Jan 2021 20:24:11

US3552005

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4)	27 Jan 2021 20:24:28

US3552005

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered '27 Jan 2021'	Heather Douds (b) (4) (b) (4)	27 Jan 2021 20:24:28

US3552005

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '08:16'	(b) (4) Heather Douds (b) (4)	27 Jan 2021 20:24:28

US3552005

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered '27 Jan 2021 08:16'	System	27 Jan 2021 20:24:28

US3552005

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:04:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4)	27 Jan 2021 20:24:44

US3552005

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:04:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '27 Jan 2021'	(b) (4) Heather Douds (b) (4)	27 Jan 2021 20:24:44

US3552005

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:04:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '08:18'	(b) (4) Heather Douds (b) (4)	27 Jan 2021 20:24:44

US3552005

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:04:59

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered '27 Jan 2021 08:18'	System	27 Jan 2021 20:24:44

US3552005

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

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Feb 2021 16:49:03

US3552005

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

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered 'I'	System	03 Feb 2021 16:49:03

US3552005

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Feb 2021 16:49:14

US3552005

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '03 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Feb 2021 16:49:14

US3552005

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Feb 2021 16:49:14

US3552005

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Feb 2021 16:49:14

US3552005

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	11 Feb 2021 20:51:00

US3552005

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered 'l'	System	11 Feb 2021 20:51:00

US3552005

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered 'I'	System	11 Feb 2021 20:51:00
DataPoint set to visible.	System	11 Feb 2021 20:51:00

US3552005

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:04:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:06:55
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:13:47

US3552005

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:06:55
User entered '22 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:13:47

US3552005

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:06:55
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:13:47

US3552005

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:04:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered 'OLD29'	System	22 Feb 2021 19:13:47

US3552005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	22 Feb 2021 19:14:09

US3552005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:06:55
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:14:09

US3552005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:06:55
User entered '22 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:14:09

US3552005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:06:55
User entered '09:52'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:14:09

US3552005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered '22 Feb 2021 09:52'	System	22 Feb 2021 19:14:09

US3552005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:06:55
User entered '98.1' F	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:14:09

US3552005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:06:55
User entered 'Oral (Oral)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:14:09

US3552005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:06:55
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:14:09

US3552005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:06:55
User entered '75'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:14:09

US3552005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered 'bpm'	System	22 Feb 2021 19:14:09

US3552005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:06:55
User entered '17'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:14:09

US3552005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered 'breaths/min'	System	22 Feb 2021 19:14:09

US3552005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:06:55
User entered '96'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:14:09

US3552005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered 'mmHg'	System	22 Feb 2021 19:14:09

US3552005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:06:55
User entered '60'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:14:09

US3552005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:04:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered 'mmHg'	System	22 Feb 2021 19:14:09

US3552005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	22 Feb 2021 19:14:31

US3552005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:06:55
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:14:31

US3552005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:06:55
User entered '22 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:14:31

US3552005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:06:55
User entered '11:03'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:14:31

US3552005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered '22 Feb 2021 11:03'	System	22 Feb 2021 19:14:31

US3552005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:06:55
User entered '98.8' F	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:14:31

US3552005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:06:55
User entered 'Oral (Oral)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:14:31

US3552005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:06:55
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:14:31

US3552005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:06:55
User entered '77'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:14:31

US3552005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered 'bpm'	System	22 Feb 2021 19:14:31

US3552005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:06:55
User entered '17'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:14:31

US3552005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered 'breaths/min'	System	22 Feb 2021 19:14:31

US3552005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:06:55
User entered '90'	(b) (4) Stanley Doublin (b) (4) (b) (4)	22 Feb 2021 19:14:31

US3552005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered 'mmHg'	System	22 Feb 2021 19:14:31

US3552005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:06:55
User entered '60'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:14:31

US3552005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:04:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered 'mmHg'	System	22 Feb 2021 19:14:31

US3552005

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:04:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:06:55
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:14:39

US3552005

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:04:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:06:55
User entered '22 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:14:39

US3552005

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:06:55
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:14:51

US3552005

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:06:55
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:14:51

US3552005

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:06:55
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:14:51

US3552005

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered 'mRNA-1273'	System	22 Feb 2021 19:14:51
DataPoint set to visible.	System	11 Feb 2021 20:51:00

US3552005

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:06:55
User entered '22 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:14:51

US3552005

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:06:55
User entered '10:33'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:14:51

US3552005

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered '22 Feb 2021 10:33'	System	22 Feb 2021 19:14:51

US3552005

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:06:55
User entered 'Left Arm (LEFT ARM)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:14:51

US3552005

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered 'ONCE'	System	22 Feb 2021 19:14:51

US3552005

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:04:59

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered 'INTRAMUSCULAR'	System	22 Feb 2021 19:14:51

US3552005

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:06:55
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:14:55

US3552005

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered 'l'	System	22 Feb 2021 19:14:55

US3552005

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:48:52
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 17:04:53

US3552005

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:48:52
User entered '01 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 17:04:53

US3552005

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:48:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 17:04:53

US3552005

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:04:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:48:52
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 17:04:53

US3552005

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:48:52
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 17:04:57

US3552005

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:04:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered 'l'	System	01 Mar 2021 17:04:57

US3552005

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:04:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:18:37
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	22 Mar 2021 20:43:41

US3552005

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered '22 Mar 2021'	(b) (4) Cassandra Zehenny (b) (4)	22 Mar 2021 20:43:41

US3552005

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered 'Clinic (Clinic)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	22 Mar 2021 20:43:41

US3552005

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:04:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered 'OLD57'	System	22 Mar 2021 20:43:41

US3552005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered 'Yes (Y)'	(b) (4) Cassandra Zehenny (b) (4)	22 Mar 2021 20:44:17

US3552005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered '22 Mar 2021'	(b) (4) Cassandra Zehenny (b) (4)	22 Mar 2021 20:44:17

US3552005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered '14:15'	(b) (4) Cassandra Zehenny (b) (4)	22 Mar 2021 20:44:17

US3552005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered '22 Mar 2021 14:15'	System	22 Mar 2021 20:44:17

US3552005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:18:37
User entered '98.1' F	Cassandra Zehenny (b) (4) (b) (4)	22 Mar 2021 20:44:17

US3552005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:18:37
User entered 'Oral (Oral)'	Cassandra Zehenny (b) (4) (b) (4)	22 Mar 2021 20:44:17

US3552005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	22 Mar 2021 20:44:17

US3552005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered '57'	(b) (4) Cassandra Zehenny (b) (4)	22 Mar 2021 20:44:17

US3552005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered 'bpm'	System	22 Mar 2021 20:44:17

US3552005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:18:37
User entered '16'	Cassandra Zehenny (b) (4) (b) (4)	22 Mar 2021 20:44:17

US3552005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered 'breaths/min'	System	22 Mar 2021 20:44:17

US3552005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:18:37
User entered '109'	Cassandra Zehenny (b) (4) (b) (4)	22 Mar 2021 20:44:17

US3552005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered 'mmHg'	System	22 Mar 2021 20:44:17

US3552005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered '70'	(b) (4) Cassandra Zehenny (b) (4)	22 Mar 2021 20:44:17

US3552005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered 'mmHg'	System	22 Mar 2021 20:44:17

US3552005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26

US3552005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:04:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26

US3552005

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:04:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered 'Yes (Y)'	(b) (4) Cassandra Zehenny (b) (4)	22 Mar 2021 20:44:23

US3552005

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:04:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:18:37
User entered '22 Mar 2021'	Cassandra Zehenny (b) (4) (b) (4)	22 Mar 2021 20:44:23

US3552005

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:18:37
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	22 Mar 2021 20:44:32

US3552005

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:18:37
User entered '22 Mar 2021'	Cassandra Zehenny (b) (4) (b) (4)	22 Mar 2021 20:44:32

US3552005

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered '14:20'	(b) (4) Cassandra Zehenny (b) (4)	22 Mar 2021 20:44:32

US3552005

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:04:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:26
User entered '22 Mar 2021 14:20'	System	22 Mar 2021 20:44:32

US3552005

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:04:59

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:56:14
DataPoint Verified.		08 Apr 2021 19:39:12
User closed query 'Per DM CLR: Per Day 201 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).		04 Apr 2021 05:37:16
Query 'Per DM CLR: Per Day 201 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'Please see AES US089' (Site from DM).	Heather Douds (b) (4)	25 Mar 2021 16:51:54
User opened query 'Per DM CLR: Per Day 201 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 09:31:58
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Signature has been broken.	(b) (4)	
	Heather Douds (b) (4)	22 Mar 2021 20:28:28
User entered 'Yes (Y)' reason for change: New Information	(b) (4)	
	Heather Douds (b) (4)	22 Mar 2021 20:28:28
User signature succeeded.	(b) (4)	
	sharon frey (b) (4)	21 Feb 2021 17:20:35
	(b) (4)	

US3552005

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:04:59

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	17 Feb 2021 21:27:10

US3552005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:59

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 10:07:25
User entered 'USA-US089-2021-mRNA-1273-P301000004'	System	23 Mar 2021 10:07:14
User entered 'New'	(b) (4), (b) (6)	23 Mar 2021 10:07:14

US3552005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:59

[Adverse event](#)

Audit	User	Time (GMT)
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)	05 Apr 2021 17:31:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	05 Apr 2021 17:31:28
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
Data point term sent to Coder	System	25 Mar 2021 17:11:33
Coding entries removed.	Heather Douds (b) (4)	25 Mar 2021 17:11:16
Signature has been broken.	(b) (4)	
	Heather Douds (b) (4)	25 Mar 2021 17:11:16
User entered 'severe anemia' reason for change:	(b) (4)	
Data Entry Error	Heather Douds (b) (4)	25 Mar 2021 17:11:16
User signature succeeded.	(b) (4)	
	sharon frey (b) (4)	23 Mar 2021 15:18:37
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal haemorrhages NEC, HLT: Intestinal haemorrhages, PT: Rectal haemorrhage, LLT: Rectal bleeding - version MedDRA\23.0.	(b) (4)	
	Coder Import (b) (4)	22 Mar 2021 20:47:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	22 Mar 2021 20:47:01
Data point term sent to Coder	System	22 Mar 2021 20:31:11
User entered 'Rectal bleeding'	Heather Douds (b) (4)	22 Mar 2021 20:30:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4)	22 Mar 2021 20:30:33

US3552005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	22 Mar 2021 20:30:33

US3552005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	22 Mar 2021 20:30:33

US3552005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:30:59
User closed query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms. If not updating the start date, please clarify. ' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 14:05:16
User closed query 'PV Query: please clarify event start date as reported, 15 Mar 2021. Per med recs/narrative, subject was admitted to hospital on 08 Mar 2021 and transferred to ICU for severe anemia ' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 14:05:12
Query 'PV Query: please clarify event start date as reported, 15 Mar 2021. Per med recs/narrative, subject was admitted to hospital on 08 Mar 2021 and transferred to ICU for severe anemia ' answered with 'updated' (Site from Safety).	Heather Douds (b) (4) (b) (4)	31 Mar 2021 17:43:36
Signature has been broken.	Heather Douds (b) (4) (b) (4)	31 Mar 2021 15:50:53
User entered '7 Mar 2021' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	31 Mar 2021 15:50:53
Query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms. If not updating the start date, please clarify. ' answered with 'Anemia did not become severe until start of symptoms which led to his hospital admission; the SAE is for severe anemia, not general anemia' (Site from Safety).	Heather Douds (b) (4) (b) (4)	31 Mar 2021 15:49:51
User opened query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms. If not updating the start date, please clarify. ' (Site from Safety).	(b) (4), (b) (6)	31 Mar 2021 12:53:27

US3552005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: please clarify event start date as reported, 15 Mar 2021. Per med recs/narrative, subject was admitted to hospital on 08 Mar 2021 and transferred to ICU for severe anemia ' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	31 Mar 2021 12:52:27
User entered '15 Mar 2021'	sharon frey (b) (4) (b) (4) Heather Douds (b) (4) (b) (4)	23 Mar 2021 15:18:37 22 Mar 2021 20:30:33

US3552005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:59

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	22 Mar 2021 20:30:33

US3552005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Mar 2021 20:30:33

US3552005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:30:59
User closed query 'V Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 14:05:20
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)	01 Apr 2021 14:05:18
Query 'V Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' answered with 'updated' (Site from Safety).	Heather Douds (b) (4) (b) (4)	31 Mar 2021 17:43:52
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 'updated' (Site from Safety).	Heather Douds (b) (4) (b) (4)	31 Mar 2021 17:43:46
Signature has been broken.	Heather Douds (b) (4) (b) (4)	31 Mar 2021 15:50:53
User entered 'No (N)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	31 Mar 2021 15:50:53
User opened query 'V Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' (Site from Safety).	(b) (4), (b) (6)	31 Mar 2021 12:53:18
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).		31 Mar 2021 12:53:13
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:18:37
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	22 Mar 2021 20:30:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 17:30:59
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	31 Mar 2021 17:44:11
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	31 Mar 2021 17:44:11
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	31 Mar 2021 15:50:53
Signature has been broken.	Heather Douds (b) (4)	31 Mar 2021 15:50:53
User entered '12 Mar 2021' reason for change: Data Entry Error	(b) (4)	
	Heather Douds (b) (4)	31 Mar 2021 15:50:53
User signature succeeded.	(b) (4)	
	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered empty.	(b) (4)	
	Heather Douds (b) (4)	22 Mar 2021 20:30:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:59

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	22 Mar 2021 20:30:33

US3552005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Mar 2021 20:30:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:59

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered 'Grade 4 (Grade 4)'	(b) (4) Heather Douds (b) (4) (b) (4)	22 Mar 2021 20:30:33

US3552005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	22 Mar 2021 20:30:33

US3552005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:59

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	22 Mar 2021 20:30:33

US3552005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	22 Mar 2021 20:30:33

US3552005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered 'l'	(b) (4) Heather Douds (b) (4) (b) (4)	22 Mar 2021 20:30:33

US3552005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
Signature has been broken.	(b) (4) Heather Douds (b) (4)	25 Mar 2021 17:05:31
User entered '08 Mar 2021' reason for change: New Information	(b) (4) Heather Douds (b) (4)	25 Mar 2021 17:05:31
User signature succeeded.	(b) (4) sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered '15 Mar 2021'	(b) (4) Heather Douds (b) (4)	22 Mar 2021 20:30:33

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
Signature has been broken.	(b) (4) Heather Douds (b) (4)	25 Mar 2021 17:05:31
User entered '12 Mar 2021' reason for change: New Information	(b) (4) Heather Douds (b) (4)	25 Mar 2021 17:05:31
User signature succeeded.	(b) (4) sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered '16 Mar 2021'	(b) (4) Heather Douds (b) (4)	22 Mar 2021 20:30:33

US3552005

Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
Signature has been broken.	(b) (4) Heather Douds (b) (4)	25 Mar 2021 17:05:31
User entered 'Yes (Y)' reason for change: New Information	(b) (4) Heather Douds (b) (4)	25 Mar 2021 17:05:31
User signature succeeded.	(b) (4) sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered 'No (N)'	(b) (4) Heather Douds (b) (4)	22 Mar 2021 20:30:33

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	29 Mar 2021 13:55:30
User closed query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	25 Mar 2021 17:08:28
Query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' answered by data change (Site from System).	System	25 Mar 2021 17:08:28
Signature has been broken.	Heather Douds (b) (4) (b) (4)	25 Mar 2021 17:08:28
User entered '1' reason for change: New Information	Heather Douds (b) (4) (b) (4)	25 Mar 2021 17:08:28
User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	25 Mar 2021 17:05:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:18:37
User entered empty.	Heather Douds (b) (4) (b) (4)	22 Mar 2021 20:30:33

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	22 Mar 2021 20:30:33

US3552005

Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	22 Mar 2021 20:30:33

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	22 Mar 2021 20:30:33

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered 'Not Related (NOT RELATED)'	(b) (4) Heather Douds (b) (4) (b) (4)	22 Mar 2021 20:30:33

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Folder: Adverse Events

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered 'Not Related (NOT RELATED)'	(b) (4) Heather Douds (b) (4) (b) (4)	22 Mar 2021 20:30:33

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Folder: Adverse Events

Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Heather Douds (b) (4) (b) (4)	22 Mar 2021 20:30:33

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Folder: Adverse Events

Form: Adverse Events (1)

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None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	22 Mar 2021 20:30:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
Signature has been broken.	(b) (4) Heather Douds (b) (4)	25 Mar 2021 17:05:31
User entered '1' reason for change: New Information	(b) (4) Heather Douds (b) (4)	25 Mar 2021 17:05:31
User signature succeeded.	(b) (4) sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered '0'	(b) (4) Heather Douds (b) (4)	22 Mar 2021 20:30:33

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 20:27:50
DataPoint Un-verified.	Heather Douds (b) (4)	08 Apr 2021 20:08:42
	(b) (4)	
Signature has been broken.	Heather Douds (b) (4)	08 Apr 2021 20:08:42
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Heather Douds (b) (4)	08 Apr 2021 20:08:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:03:33
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.		07 Apr 2021 11:56:05
' (Site from DM).		
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:29
	(b) (4)	
Query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.	Cassandra Zehenny (b) (4)	05 Apr 2021 15:56:54
' answered with 'updated' (Site from DM).	(b) (4)	
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	05 Apr 2021 15:56:49
	(b) (4)	
Signature has been broken.	Cassandra Zehenny (b) (4)	05 Apr 2021 15:56:49
	(b) (4)	
User entered '0' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	05 Apr 2021 15:56:49
	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.	(b) (4), (b) (6)	05 Apr 2021 09:55:07
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
	(b) (4)	
User entered '1'	Heather Douds (b) (4)	22 Mar 2021 20:30:33
	(b) (4)	

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EAB) (1725)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 17:30:59
Signature has been broken.	Heather Douds (b) (4)	31 Mar 2021 17:44:11
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Heather Douds (b) (4)	31 Mar 2021 17:44:11
Data Entry Error	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Heather Douds (b) (4)	22 Mar 2021 20:30:33
	(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)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	22 Mar 2021 20:30:33

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User closed query '. PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).		01 Apr 2021 14:05:33
User closed query 'PV Query: Please review if prolapsed, inflamed internal hemorrhoids, acute hypoxic respiratory failure, congestive heart failure exacerbation, acute renal failure meet criteria for SAE reporting ' (Site from Safety).		01 Apr 2021 14:05:27
User closed query ' PV Query: please clarify date of hemorrhoid excision procedure; medical records note it was performed on 07 Mar 2021, but subject was not admitted to hospital until 08 Mar 2021 ' (Site from Safety).		01 Apr 2021 14:05:24
Query '. PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' answered with 'COVID testing was not listed in medical records' (Site from Safety).	Heather Douds (b) (4)	31 Mar 2021 17:48:52
Query 'PV Query: Please review if prolapsed, inflamed internal hemorrhoids, acute hypoxic respiratory failure, congestive heart failure exacerbation, acute renal failure meet criteria for SAE reporting ' answered with 'With the exception of hemorrhoids, these are a related to the severe anemia and therefore do not need to be captured as separate SAEs. Hemorrhoids on their own would not meet SAE criteria' (Site from Safety).	Heather Douds (b) (4)	31 Mar 2021 17:45:26
Query ' PV Query: please clarify date of hemorrhoid excision procedure; medical records note it was performed on 07 Mar 2021, but subject was not admitted to hospital until 08 Mar 2021 ' answered with 'Data is entered as per medical records' (Site from Safety).	Heather Douds (b) (4)	31 Mar 2021 17:44:31

US3552005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:59

[Narrative](#)

Audit	User	Time (GMT)
User opened query '. PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	31 Mar 2021 12:52:53
User opened query 'PV Query: Please review if prolapsed, inflamed internal hemorrhoids, acute hypoxic respiratory failure, congestive heart failure exacerbation, acute renal failure meet criteria for SAE reporting ' (Site from Safety).		31 Mar 2021 12:52:43
User opened query ' PV Query: please clarify date of hemorrhoid excision procedure; medical records note it was performed on 07 Mar 2021, but subject was not admitted to hospital until 08 Mar 2021 ' (Site from Safety).		31 Mar 2021 12:52:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	29 Mar 2021 13:55:30

US3552005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:59

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT ADMITTED TO HOSPITAL FOR RECTAL BLEEDING. MEDICAL RECORD REQUEST SUBMITTED, WILL SEND AS SOON AS WE RECEIVE THEM. UPDATE 3/25/21: SUBJECT PRESENTED TO ED ON 3/8 WITH COMPLAINTS OF WORSENING SOB, FATIGUE, AND LIGHTHEADEDNESS OVER THE PAST WEEK, AS WELL AS BRIGHT RED HEMORRHOIDAL BLEEDING THAT HAD BEEN INTERMITTENT. BLOODWORK WAS DONE, FOUND TO HAVE HEMOGLOBIN OF 3.6; ADMITTED TO ICU FOR SEVERE ANEMIA. RECEIVED 6 UNITS OF BLOOD VIA TRANSFUSION, AS WELL AS UPPER GI ENDOSCOPY AND COLONOSCOPY, WHICH FOUND PROLAPSED, INFLAMED INTERNAL HEMORRHOIDS. ALSO NOTED TO HAVE ACUTE HYPOXIC RESPIRATORY FAILURE DUE TO CONGESTIVE HEART FAILURE EXACERBATION WITH BILATERAL PULMONARY EDEMA on X-ray, AS WELL AS ACUTE RENAL FAILURE DUE TO VOLUME DEPLETION. DISCHARGED HOME ON 3L O2 AT NIGHT AND AS NEEDED WITH EXERTION, AS WELL AS MEDICATION CHANGES (SEE CON MEDS). WILL SEND MEDICAL RECORDS.'	Heather Douds (b) (4)	25 Mar 2021 18:44:45
reason for change: New Information Signature has been broken.	Heather Douds (b) (4)	25 Mar 2021 17:05:31

US3552005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:59

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT ADMITTED TO HOSPITAL FOR RECTAL BLEEDING. MEDICAL RECORD REQUEST SUBMITTED, WILL SEND AS SOON AS WE RECEIVE THEM. Update 3/25/21: Subject presented to ED on 3/8 with complaints of worsening SOB, fatigue, and lightheadedness over the past week, as well as bright red hemorrhoidal bleeding that had been intermittent. Bloodwork was done, found to have hemoglobin of 3.6; admitted to ICU for severe anemia. Received 6 units of blood via transfusion, as well as upper GI endoscopy and colonoscopy, which found prolapsed, inflamed internal hemorrhoids. Also noted to have acute hypoxic respiratory failure due to congestive heart failure exacerbation with bilateral pulmonary edema, as well as acute renal failure due to volume depletion. Discharged home on 3L O2 at night and as needed with exertion, as well as medication changes (see con meds). Will send medical records today.' reason for change: New Information	Heather Douds (b) (4)	25 Mar 2021 17:05:31
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	(b) (4) System	22 Mar 2021 20:33:18
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	22 Mar 2021 20:33:18
User entered 'subject admitted to hospital for rectal bleeding. medical record request submitted, will send as soon as we receive them.' reason for change: New Information	Cassandra Zehenny (b) (4)	22 Mar 2021 20:33:18
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	22 Mar 2021 20:30:33
User entered empty.	Heather Douds (b) (4)	22 Mar 2021 20:30:33

US3552005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	22 Mar 2021 20:30:33

US3552005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	22 Mar 2021 20:30:33

US3552005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:04:59

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Mar 2021 17:05:31
User entered 'O'	System	22 Mar 2021 20:30:33

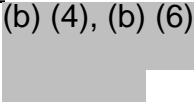
US3552005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) 	27 Apr 2021 14:34:09

US3552005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:09
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal vascular conditions, HLT: Haemorrhoids and gastrointestinal varices (excl oesophageal), PT: Haemorrhoids, LLT: Internal hemorrhoids - version MedDRA\23.0.	Coder Import (b) (4)	25 Mar 2021 19:17:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Mar 2021 19:17:29
Data point term sent to Coder	System	25 Mar 2021 19:01:39
User entered 'internal hemorrhoids'	Heather Douds (b) (4)	25 Mar 2021 19:00:58

US3552005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:09
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:00:58

US3552005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:09
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:00:58

US3552005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:09
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:00:58

US3552005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:09
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '7 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:00:58

US3552005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:09
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:00:58

US3552005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:09
User entered empty.	System	25 Mar 2021 19:00:58

US3552005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:09
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:00:58

US3552005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:09
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '12 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:00:58

US3552005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:09
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:00:58

US3552005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:09
User entered empty.	System	25 Mar 2021 19:00:58

US3552005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:09
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:00:58

US3552005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:09
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:00:58

US3552005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:09
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:00:58

US3552005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:09
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:00:58

US3552005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:09
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:00:58

US3552005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:09
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:00:58

US3552005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:59

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:09
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:00:58

US3552005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:09
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:00:58

US3552005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:09
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:00:58

US3552005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:09
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:00:58

US3552005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:09
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:00:58

US3552005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:09
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:00:58

US3552005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:09
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Not Related (NOT RELATED)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:00:58

US3552005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:09
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Not Related (NOT RELATED)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:00:58

US3552005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:09
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:00:58

US3552005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:09
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:00:58

US3552005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:09
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:00:58

US3552005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:09
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'l'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:00:58

US3552005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:09
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:00:58

US3552005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:09
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:00:58

US3552005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:09
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:00:58

US3552005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:59

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:09
User entered '0'	System	25 Mar 2021 19:00:58

US3552005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:09
User entered '1'	System	25 Mar 2021 19:00:58

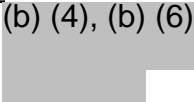
US3552005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:04:59

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) 	27 Apr 2021 14:34:09

US3552005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 14:34:32

US3552005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:32
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLT: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Acute respiratory failure, LLT: Acute respiratory failure - version MedDRA\23.0.	Coder Import (b) (4)	14 Apr 2021 18:20:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Apr 2021 18:20:50
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLT: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Respiratory failure, LLT: Hypoxic respiratory failure - version MedDRA\23.0.	Coder Import (b) (4)	26 Mar 2021 20:21:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	26 Mar 2021 20:21:31
Data point term sent to Coder	System	26 Mar 2021 20:06:12
User closed query 'Per CDM Coding: for AE term ACUTE HYPOXIC RESPIRATORY FAILURE DUE TO CONGESTIVE HEART FAILURE, Multiple medical concepts are reported. Please split and report each term on separate lines to capture coding for all the terms, e.g. one of ACUTE HYPOXIC RESPIRATORY FAILURE and one of CONGESTIVE HEART FAILURE etc.	System	26 Mar 2021 20:05:39
' (Site from System).		
Query 'Per CDM Coding: for AE term ACUTE HYPOXIC RESPIRATORY FAILURE DUE TO CONGESTIVE HEART FAILURE, Multiple medical concepts are reported. Please split and report each term on separate lines to capture coding for all the terms, e.g. one of ACUTE HYPOXIC RESPIRATORY FAILURE and one of CONGESTIVE HEART FAILURE etc.	Cassandra Zehenny (b) (4)	26 Mar 2021 20:05:39
' answered with 'updated' (Site from System).		
Data point term sent to Coder	System	26 Mar 2021 20:05:11

US3552005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:59

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'ACUTE HYPOXIC RESPIRATORY FAILURE' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	26 Mar 2021 20:04:31
User opened query 'Per CDM Coding: for AE term ACUTE HYPOXIC RESPIRATORY FAILURE DUE TO CONGESTIVE HEART FAILURE, Multiple medical concepts are reported. Please split and report each term on separate lines to capture coding for all the terms, e.g. one of ACUTE HYPOXIC RESPIRATORY FAILURE and one of CONGESTIVE HEART FAILURE etc. '(Site from System).	Coder Import (b) (4)	26 Mar 2021 09:36:43
Data point term sent to Coder	System	25 Mar 2021 19:02:40
User entered 'Acute hypoxic respiratory failure due to congestive heart failure'	Heather Douds (b) (4)	25 Mar 2021 19:02:09

US3552005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:32
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:09

US3552005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:32
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:09

US3552005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:32
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:09

US3552005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:32
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '8 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:09

US3552005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:32
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:09

US3552005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:32
User entered empty.	System	25 Mar 2021 19:02:09

US3552005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:32
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:09

US3552005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:32
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '12 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:09

US3552005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:32
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:09

US3552005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:32
User entered empty.	System	25 Mar 2021 19:02:09

US3552005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:32
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:09

US3552005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:32
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:09

US3552005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:32
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:09

US3552005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:32
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:09

US3552005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:32
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:09

US3552005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:32
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:09

US3552005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:32
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:09

US3552005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:32
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:09

US3552005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:32
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:09

US3552005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:32
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:09

US3552005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:32
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:09

US3552005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:32
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:09

US3552005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:32
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Not Related (NOT RELATED)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:09

US3552005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:32
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Not Related (NOT RELATED)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:09

US3552005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:32
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:09

US3552005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:32
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:09

US3552005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:32
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'l'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:09

US3552005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:32
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:09

US3552005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:32
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:09

US3552005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:32
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:09

US3552005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:32
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:09

US3552005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:59

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:32
User entered '0'	System	25 Mar 2021 19:02:09

US3552005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:59

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:32
User entered '1'	System	25 Mar 2021 19:02:09

US3552005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:04:59

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 14:34:32

US3552005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 14:38:48

US3552005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Acute kidney injury, LLT: Acute renal failure - version MedDRA\23.0.	Coder Import (b) (4)	25 Mar 2021 19:04:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Mar 2021 19:04:33
Data point term sent to Coder	System	25 Mar 2021 19:03:41
User entered 'acute renal failure'	Heather Douds (b) (4)	25 Mar 2021 19:02:47

US3552005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:47

US3552005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:47

US3552005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:47

US3552005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '8 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:47

US3552005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:47

US3552005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:48
User entered empty.	System	25 Mar 2021 19:02:47

US3552005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:47

US3552005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '12 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:47

US3552005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:47

US3552005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:48
User entered empty.	System	25 Mar 2021 19:02:47

US3552005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:47

US3552005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:47

US3552005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:47

US3552005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:47

US3552005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:47

US3552005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:47

US3552005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:47

US3552005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:47

US3552005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:47

US3552005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:47

US3552005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:47

US3552005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:47

US3552005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Not Related (NOT RELATED)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:47

US3552005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Not Related (NOT RELATED)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:47

US3552005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:47

US3552005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:47

US3552005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'l'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:47

US3552005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:47

US3552005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:47

US3552005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:47

US3552005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:02:47

US3552005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:59

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:48
User entered '0'	System	25 Mar 2021 19:02:47

US3552005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:48
User entered '1'	System	25 Mar 2021 19:02:47

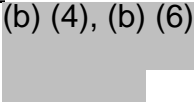
US3552005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:04:59

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) 	27 Apr 2021 14:38:48

US3552005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:59

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User coded data point as SOC: Gastrointestinal disorders, HLGT: Anal and rectal conditions NEC, HLT: Anal and rectal pains, PT: Proctalgia, LLT: Rectal pain - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	25 Mar 2021 19:04:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 19:04:32
Data point term sent to Coder	System	25 Mar 2021 19:03:41
User entered 'Rectal pain'	Heather Douds (b) (4)	25 Mar 2021 19:03:23
	(b) (4)	

US3552005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 19:03:23

US3552005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:03:23

US3552005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:03:23

US3552005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '8 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:03:23

US3552005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:59

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:03:23

US3552005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 19:03:23

US3552005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:03:23

US3552005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:03:23

US3552005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:59

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:03:23

US3552005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 19:03:23

US3552005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:59

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 19:03:23

US3552005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:03:23

US3552005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:59

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:03:23

US3552005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:03:23

US3552005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:03:23

US3552005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:03:23

US3552005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:59

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:03:23

US3552005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:03:23

US3552005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:03:23

US3552005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:03:23

US3552005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:03:23

US3552005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:59

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:03:23

US3552005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Not Related (NOT RELATED)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:03:23

US3552005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Not Related (NOT RELATED)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:03:23

US3552005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:03:23

US3552005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:59

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:03:23

US3552005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'l'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:03:23

US3552005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:03:23

US3552005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:59

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:03:23

US3552005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:03:23

US3552005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:59

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:03:23

US3552005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Mar 2021 19:03:23

US3552005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:04:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Mar 2021 19:03:23

US3552005

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 14:40:02

US3552005

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal vascular conditions, HLT: Haemorrhoids and gastrointestinal varices (excl oesophageal), PT: Haemorrhoids, LLT: External hemorrhoids - version MedDRA\23.0.	Coder Import (b) (4)	25 Mar 2021 19:07:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Mar 2021 19:07:30
Data point term sent to Coder	System	25 Mar 2021 19:06:46
User entered 'External hemorrhoids'	Heather Douds (b) (4)	25 Mar 2021 19:05:53

US3552005

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:05:53

US3552005

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:05:53

US3552005

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:05:53

US3552005

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '7 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:05:53

US3552005

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:05:53

US3552005

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:02
User entered empty.	System	25 Mar 2021 19:05:53

US3552005

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:05:53

US3552005

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '12 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:05:53

US3552005

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:05:53

US3552005

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:02
User entered empty.	System	25 Mar 2021 19:05:53

US3552005

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:05:53

US3552005

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:05:53

US3552005

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:05:53

US3552005

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:05:53

US3552005

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:05:53

US3552005

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:05:53

US3552005

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:05:53

US3552005

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:05:53

US3552005

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:05:53

US3552005

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:05:53

US3552005

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:05:53

US3552005

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:05:53

US3552005

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Not Related (NOT RELATED)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:05:53

US3552005

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Not Related (NOT RELATED)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:05:53

US3552005

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:05:53

US3552005

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:59

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:05:53

US3552005

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:05:53

US3552005

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'l'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:05:53

US3552005

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:05:53

US3552005

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:05:53

US3552005

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:05:53

US3552005

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:59

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:02
User entered '0'	System	25 Mar 2021 19:05:53

US3552005

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:02
User entered 'I'	System	25 Mar 2021 19:05:53

US3552005

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:04:59

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 14:40:02

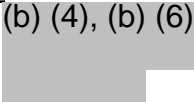
US3552005

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) 	27 Apr 2021 14:41:37

US3552005

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:41:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\23.0.	Coder Import (b) (4)	25 Mar 2021 19:08:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Mar 2021 19:08:29
Data point term sent to Coder	System	25 Mar 2021 19:07:49
User entered 'shortness of breath'	Heather Douds (b) (4)	25 Mar 2021 19:06:59

US3552005

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:41:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:06:59

US3552005

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:41:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:06:59

US3552005

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:41:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:06:59

US3552005

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:41:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '1 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:06:59

US3552005

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:41:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:06:59

US3552005

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:41:37
User entered empty.	System	25 Mar 2021 19:06:59

US3552005

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:41:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:06:59

US3552005

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:41:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '12 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:06:59

US3552005

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:41:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:06:59

US3552005

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:41:37
User entered empty.	System	25 Mar 2021 19:06:59

US3552005

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:41:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:06:59

US3552005

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:41:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:06:59

US3552005

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:41:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:06:59

US3552005

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:41:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:06:59

US3552005

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:41:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:06:59

US3552005

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:41:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:06:59

US3552005

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:41:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:06:59

US3552005

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:41:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:06:59

US3552005

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:41:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:06:59

US3552005

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:41:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:06:59

US3552005

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:41:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:06:59

US3552005

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:41:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:06:59

US3552005

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:41:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Not Related (NOT RELATED)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:06:59

US3552005

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:41:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Not Related (NOT RELATED)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:06:59

US3552005

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:41:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:06:59

US3552005

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:59

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:41:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:06:59

US3552005

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:41:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'l'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:06:59

US3552005

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:41:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:06:59

US3552005

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:41:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:06:59

US3552005

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:41:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:06:59

US3552005

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:41:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:06:59

US3552005

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:59

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:41:37
User entered '0'	System	25 Mar 2021 19:06:59

US3552005

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:41:37
User entered '1'	System	25 Mar 2021 19:06:59

US3552005

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:04:59

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 14:41:37

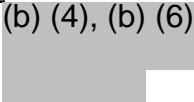
US3552005

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) 	27 Apr 2021 14:42:03

US3552005

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:03
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
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)	25 Mar 2021 19:26:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Mar 2021 19:26:30
Data point term sent to Coder	System	25 Mar 2021 19:10:51
User entered 'Fatigue'	Heather Douds (b) (4)	25 Mar 2021 19:10:05

US3552005

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:03
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:10:05

US3552005

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:03
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:10:05

US3552005

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:03
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:10:05

US3552005

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:03
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '1 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:10:05

US3552005

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:03
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:10:05

US3552005

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:03
User entered empty.	System	25 Mar 2021 19:10:05

US3552005

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:03
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:10:05

US3552005

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:03
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	25 Mar 2021 19:10:24
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	25 Mar 2021 19:10:24
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	25 Mar 2021 19:10:24
User entered '12 Mar 2021' reason for change: Data Entry Error	Heather Douds (b) (4)	25 Mar 2021 19:10:24
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	25 Mar 2021 19:10:05
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	25 Mar 2021 19:10:05
User entered empty.	Heather Douds (b) (4)	25 Mar 2021 19:10:05
	(b) (4)	

US3552005

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:03
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:10:05

US3552005

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:03
User entered empty.	System	25 Mar 2021 19:10:05

US3552005

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:03
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:10:05

US3552005

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:03
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:10:05

US3552005

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:03
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:10:05

US3552005

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:03
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:10:05

US3552005

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:03
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:10:05

US3552005

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:03
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:10:05

US3552005

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:03
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:10:05

US3552005

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:03
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:10:05

US3552005

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:03
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:10:05

US3552005

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:03
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:10:05

US3552005

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:03
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:10:05

US3552005

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:03
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:10:05

US3552005

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:03
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Not Related (NOT RELATED)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:10:05

US3552005

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:03
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Not Related (NOT RELATED)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:10:05

US3552005

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:03
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:10:05

US3552005

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:03
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:10:05

US3552005

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:03
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'l'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:10:05

US3552005

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:03
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:10:05

US3552005

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:03
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:10:05

US3552005

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:03
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:10:05

US3552005

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:03
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:10:05

US3552005

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:59

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:03
User entered '0'	System	25 Mar 2021 19:10:05

US3552005

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:03
User entered '1'	System	25 Mar 2021 19:10:05

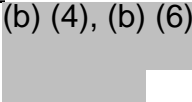
US3552005

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:04:59

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) 	27 Apr 2021 14:42:03

US3552005

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:27

US3552005

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:27
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Dizziness, LLT: Lightheadedness - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	25 Mar 2021 19:12:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 19:12:31
Data point term sent to Coder	System	25 Mar 2021 19:11:53
User entered 'Lightheadedness'	Heather Douds (b) (4)	25 Mar 2021 19:11:17
	(b) (4)	

US3552005

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:27
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:11:17

US3552005

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:27
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:11:17

US3552005

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:27
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:11:17

US3552005

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:27
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '1 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:11:17

US3552005

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:27
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:11:17

US3552005

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:27
User entered empty.	System	25 Mar 2021 19:11:17

US3552005

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:27
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:11:17

US3552005

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:27
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '12 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:11:17

US3552005

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:27
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:11:17

US3552005

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:27
User entered empty.	System	25 Mar 2021 19:11:17

US3552005

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:27
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:11:17

US3552005

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:27
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:11:17

US3552005

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:27
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:11:17

US3552005

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:27
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:11:17

US3552005

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:27
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:11:17

US3552005

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:27
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:11:17

US3552005

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:27
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:11:17

US3552005

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:27
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:11:17

US3552005

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:27
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:11:17

US3552005

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:27
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:11:17

US3552005

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:27
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:11:17

US3552005

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:27
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:11:17

US3552005

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:27
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Not Related (NOT RELATED)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:11:17

US3552005

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:27
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Not Related (NOT RELATED)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:11:17

US3552005

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:27
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:11:17

US3552005

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:27
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:11:17

US3552005

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:27
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'l'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:11:17

US3552005

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:27
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:11:17

US3552005

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:27
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:11:17

US3552005

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:27
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:11:17

US3552005

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:27
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:30:59
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:11:17

US3552005

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:59

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:27
User entered '0'	System	25 Mar 2021 19:11:17

US3552005

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:27
User entered 'I'	System	25 Mar 2021 19:11:17

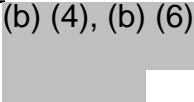
US3552005

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:04:59

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) 	27 Apr 2021 14:42:27

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:04:59

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:56:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:39:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:36:17

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:04:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 21:40:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 21:40:15
Data point term sent to Coder	System	11 Aug 2020 21:39:26
User entered 'Lipitor'	Mikayla Frye (b) (4)	11 Aug 2020 21:39:23

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:04:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:39:23

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:04:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Hypercholesterolemia'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:39:23

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:04:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '20'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:39:23

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:04:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'mg (mg)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:39:23

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:04:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:39:23

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:04:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'once daily (QD)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:39:23

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:04:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:39:23

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:04:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Oral (ORAL)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:39:23

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:04:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:39:23

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 09:28:58
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Correct as entered.' (Site from System).	Mikayla Frye (b) (4)	11 Aug 2020 21:40:09
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 21:39:23
User entered 'UN UNK 1995'	Mikayla Frye (b) (4)	11 Aug 2020 21:39:23

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:39:23

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:39:23

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:04:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:39:23

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:04:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:39:23

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:04:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	11 Aug 2020 21:39:23

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	11 Aug 2020 21:39:23

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 21:39:23

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:04:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: NEBIVOLOL HYDROCHLORIDE, PRODUCTSYNONYM: BYSTOLIC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	11 Aug 2020 21:43:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 21:43:17
Data point term sent to Coder	System	11 Aug 2020 21:42:30
User entered 'Bystolic'	Mikayla Frye (b) (4)	11 Aug 2020 21:41:33

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:04:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:41:33

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:04:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Hypertension'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:41:33

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:04:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '20'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:41:33

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:04:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'mg (mg)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:41:33

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:04:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:41:33

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:04:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'once daily (QD)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:41:33

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:04:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:41:33

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:04:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Oral (ORAL)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:41:33

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:04:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:41:33

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 09:32:50
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Date is correct as entered.' (Site from System).	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:56:42
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 21:41:33
User entered 'UN UNK 2000'	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:41:33

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:41:33

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:41:33

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:04:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:41:33

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:04:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:41:33

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:04:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	11 Aug 2020 21:41:33

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Aug 2020 21:41:33

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 21:41:33

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:04:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: ENALAPRILAT, PRODUCTSYNONYM: VASOTEC [ENALAPRILAT] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Aug 2020 01:06:15
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 Aug 2020 01:06:15
Data point term sent to Coder	System	11 Aug 2020 21:43:31
User entered 'Vasotec'	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:42:32

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:04:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:42:32

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:04:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Hypertension'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:42:32

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:04:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '20'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:42:32

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:04:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'mg (mg)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:42:32

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:04:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:42:32

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:04:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'once daily (QD)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:42:32

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:04:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:42:32

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:04:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Oral (ORAL)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:42:32

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:04:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:42:32

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 09:33:07
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Date is correct as entered.' (Site from System).	Mikayla Frye (b) (4)	11 Aug 2020 21:56:55
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 21:42:32
User entered 'UN UNK 2000'	Mikayla Frye (b) (4)	11 Aug 2020 21:42:32

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:42:32

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:42:32

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:04:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:42:32

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:04:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:42:32

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:04:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	11 Aug 2020 21:42:32

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	11 Aug 2020 21:42:32

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 21:42:32

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:04:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	11 Aug 2020 21:45:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 21:45:19
Data point term sent to Coder	System	11 Aug 2020 21:44:33
User entered 'Spironolactone'	Mikayla Frye (b) (4)	11 Aug 2020 21:43:48

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:04:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:43:48

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:04:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Hypertension'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:43:48

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:04:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '25'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:43:48

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:04:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'mg (mg)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:43:48

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:04:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:43:48

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:04:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'once daily (QD)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:43:48

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:04:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:43:48

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:04:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Oral (ORAL)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:43:48

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:04:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:43:48

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Date is correct as entered.' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 09:33:55
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Mikayla Frye (b) (4)	11 Aug 2020 21:57:04
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
User entered 'UN UNK 1985'	System	11 Aug 2020 21:43:48
	Mikayla Frye (b) (4)	11 Aug 2020 21:43:48
	(b) (4)	

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:43:48

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:43:48

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:04:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:43:48

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:04:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:43:48

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:04:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	11 Aug 2020 21:43:48

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Aug 2020 21:43:48

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 21:43:48

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:04:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
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.	(b) (4) Coder Import (b) (4) (b) (4)	13 Aug 2020 13:44:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 13:44:27
Data point term sent to Coder	System	11 Aug 2020 21:46:34
Data point term sent to Coder	System	11 Aug 2020 21:45:34
Data point term sent to Coder	System	11 Aug 2020 21:44:33
User entered 'Lasix'	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:44:02

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:04:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Aug 2020 21:44:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 21:44:33
User entered 'No (N)' reason for change: Data Entry Error	Mikayla Frye (b) (4)	11 Aug 2020 21:44:33
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Aug 2020 21:44:02
User entered empty.	System	11 Aug 2020 21:44:02
	Mikayla Frye (b) (4)	11 Aug 2020 21:44:02
	(b) (4)	

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:04:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
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	11 Aug 2020 21:45:15
User entered 'Hypertension' reason for change: Data Entry Error	Mikayla Frye (b) (4)	11 Aug 2020 21:45:15
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	11 Aug 2020 21:44:02
	Mikayla Frye (b) (4)	11 Aug 2020 21:44:02
	(b) (4)	

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:04:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
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	11 Aug 2020 21:46:14
User entered '40' reason for change: Data Entry Error	Mikayla Frye (b) (4)	11 Aug 2020 21:46:14
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	11 Aug 2020 21:44:02
	Mikayla Frye (b) (4)	11 Aug 2020 21:44:02
	(b) (4)	

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:04:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
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	11 Aug 2020 21:46:14
User entered 'mg (mg)' reason for change: Data Entry Error	Mikayla Frye (b) (4)	11 Aug 2020 21:46:14
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	11 Aug 2020 21:44:02
	Mikayla Frye (b) (4)	11 Aug 2020 21:44:02
	(b) (4)	

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:04:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:44:02

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:04:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	11 Aug 2020 21:46:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 21:46:14
User entered 'once daily (QD)' reason for change: Data Entry Error	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:46:14
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 21:44:02
User entered empty.	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:44:02

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:04:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:44:02

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:04:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Aug 2020 21:46:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 21:46:14
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Mikayla Frye (b) (4)	11 Aug 2020 21:46:14
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Aug 2020 21:44:02
User entered empty.	System	11 Aug 2020 21:44:02
	Mikayla Frye (b) (4)	11 Aug 2020 21:44:02
	(b) (4)	

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:04:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:44:02

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Data entered is correct.' (Site from System).	(b) (4), (b) (6) Mikayla Frye (b) (4) (b) (4)	12 Aug 2020 09:34:17 11 Aug 2020 21:46:29
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 21:46:14
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	11 Aug 2020 21:46:14
User entered 'UN UNK 2004' reason for change: Data Entry Error	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:46:14
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	11 Aug 2020 21:44:02
User entered empty.	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:44:02

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:44:02

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:22
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
Signature has been broken.	(b) (4)	
	Heather Douds (b) (4)	25 Mar 2021 18:45:20
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Heather Douds (b) (4)	25 Mar 2021 18:45:20
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 21:46:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 21:46:14
User entered 'Yes (Y)' reason for change: Data Entry Error	Mikayla Frye (b) (4)	11 Aug 2020 21:46:14
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 21:44:02
User entered empty.	Mikayla Frye (b) (4)	11 Aug 2020 21:44:02
	(b) (4)	

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:22
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
Signature has been broken.	(b) (4)	
	Heather Douds (b) (4)	25 Mar 2021 18:45:20
	(b) (4)	
User entered '8 Mar 2021' reason for change: New Information	Heather Douds (b) (4)	25 Mar 2021 18:45:20
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
	(b) (4)	
User entered empty.	Mikayla Frye (b) (4)	11 Aug 2020 21:44:02
	(b) (4)	

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:04:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Aug 2020 21:46:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 21:46:14
User entered 'No (N)' reason for change: Data Entry Error	Mikayla Frye (b) (4)	11 Aug 2020 21:46:14
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Aug 2020 21:44:02
User entered empty.	System	11 Aug 2020 21:44:02
	Mikayla Frye (b) (4)	11 Aug 2020 21:44:02
	(b) (4)	

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:04:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:22
User entered 'l'	System	11 Aug 2020 21:46:14
User entered empty.	System	11 Aug 2020 21:44:02

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:22
User entered 'l'	System	11 Aug 2020 21:46:14
User entered empty.	System	11 Aug 2020 21:44:02

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:22
User entered '804 (804)'	System	11 Aug 2020 21:46:14
User entered empty.	System	11 Aug 2020 21:44:02

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:04:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 21:49:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 21:49:16
Data point term sent to Coder	System	11 Aug 2020 21:48:36
User entered 'Eliquis'	Mikayla Frye (b) (4)	11 Aug 2020 21:47:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:04:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:47:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:04:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Atrial fibrillation'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:47:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:04:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '5'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:47:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:04:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'mg (mg)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:47:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:04:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:47:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:04:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'twice daily (BID)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:47:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:04:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:47:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:04:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Oral (ORAL)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:47:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:04:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:47:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 09:35:25
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Date is correct as entered.' (Site from System).	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:57:15
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 21:47:45
User entered 'UN UNK 2008'	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:47:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:47:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:37
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
Signature has been broken.	(b) (4)	
	Heather Douds (b) (4)	25 Mar 2021 18:30:45
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Heather Douds (b) (4)	25 Mar 2021 18:30:45
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
	(b) (4)	
User entered 'Yes (Y)'	Mikayla Frye (b) (4)	11 Aug 2020 21:47:45
	(b) (4)	

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:37
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
Signature has been broken.	(b) (4)	
	Heather Douds (b) (4)	25 Mar 2021 18:30:45
	(b) (4)	
User entered '8 Mar 2021' reason for change: New Information	Heather Douds (b) (4)	25 Mar 2021 18:30:45
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
	(b) (4)	
User entered empty.	Mikayla Frye (b) (4)	11 Aug 2020 21:47:45
	(b) (4)	

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:04:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:47:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:04:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:37
User entered '2'	System	11 Aug 2020 21:47:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:37
User entered 'I'	System	11 Aug 2020 21:47:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:37
User entered '804 (804)'	System	11 Aug 2020 21:47:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:04:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: OTHER ANTIHYPERTENSIVES, ATC: ANTIHYPERTENSIVES FOR PULMONARY ARTERIAL HYPERTENSION, PRODUCT: TADALAFIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 10:54:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 10:54:23
Data point term sent to Coder	System	11 Aug 2020 21:51:42
User entered 'Tadalafil'	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:50:52

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:04:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:50:52

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:04:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Pulmonary hypertension'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:50:52

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:04:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '20'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:50:52

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:04:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'mg (mg)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:50:52

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:04:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:50:52

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:04:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'twice daily (BID)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:50:52

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:04:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:50:52

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:04:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Oral (ORAL)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:50:52

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:04:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:50:52

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Data is correct as entered.' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 09:36:29
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	Mikayla Frye (b) (4)	11 Aug 2020 21:51:28
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered 'UN Jan 2020' reason for change: Data Entry Error	System	11 Aug 2020 21:51:06
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 21:51:06
User entered ' Jan 2020' (non-conformant).	Mikayla Frye (b) (4)	11 Aug 2020 21:51:06
	(b) (4)	
	System	11 Aug 2020 21:50:52
	Mikayla Frye (b) (4)	11 Aug 2020 21:50:52
	(b) (4)	

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:50:52

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:41
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
Signature has been broken.	(b) (4)	
	Heather Douds (b) (4)	25 Mar 2021 18:45:38
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Heather Douds (b) (4)	25 Mar 2021 18:45:38
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
	(b) (4)	
User entered 'Yes (Y)'	Mikayla Frye (b) (4)	11 Aug 2020 21:50:52
	(b) (4)	

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:41
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
Signature has been broken.	(b) (4)	
	Heather Douds (b) (4)	25 Mar 2021 18:45:38
	(b) (4)	
User entered '8 Mar 2021' reason for change: New Information	Heather Douds (b) (4)	25 Mar 2021 18:45:38
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
	(b) (4)	
User entered empty.	Mikayla Frye (b) (4)	11 Aug 2020 21:50:52
	(b) (4)	

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:04:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:50:52

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:04:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:41
User entered '2'	System	11 Aug 2020 21:50:52

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:41
User entered 'I'	System	11 Aug 2020 21:50:52

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:41
User entered '804 (804)'	System	11 Aug 2020 21:50:52

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:04:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: OTHER ANTIHYPERTENSIVES, ATC: ANTIHYPERTENSIVES FOR PULMONARY ARTERIAL HYPERTENSION, PRODUCT: AMBRISANTAN, PRODUCTSYNONYM: LETAIRIS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	11 Aug 2020 21:54:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 21:54:13
Data point term sent to Coder	System	11 Aug 2020 21:52:47
User entered 'Letairis'	Mikayla Frye (b) (4)	11 Aug 2020 21:52:38

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:04:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:52:38

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:04:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Pulmonary hypertension'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:52:38

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:04:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '10'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:52:38

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:04:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'mg (mg)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:52:38

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:04:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:52:38

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:04:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'once daily (QD)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:52:38

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:04:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:52:38

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:04:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Oral (ORAL)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:52:38

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:04:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:52:38

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	12 Aug 2020 09:36:52
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Date is correct as entered.' (Site from System).	(b) (4), (b) (6)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Mikayla Frye (b) (4)	11 Aug 2020 21:57:28
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 21:52:38
User entered 'UN Jan 2020'	Mikayla Frye (b) (4)	11 Aug 2020 21:52:38
	(b) (4)	

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:52:38

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:52:38

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:04:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:52:38

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:04:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:52:38

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:04:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	11 Aug 2020 21:52:38

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Aug 2020 21:52:38

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 21:52:38

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:04:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	11 Aug 2020 21:56:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 21:56:22
Data point term sent to Coder	System	11 Aug 2020 21:54:50
User entered 'Metformin'	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:54:20

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:04:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:54:20

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:04:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Type 2 Diabetes'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:54:20

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:04:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '50'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:54:20

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:04:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'mg (mg)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:54:20

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:04:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:54:20

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:04:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'once daily (QD)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:54:20

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:04:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:54:20

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:04:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Oral (ORAL)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:54:20

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:04:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:54:20

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 09:38:22
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Date is correct as entered.' (Site from System).	Mikayla Frye (b) (4)	11 Aug 2020 21:57:40
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 21:54:20
User entered 'UN UNK 1997'	Mikayla Frye (b) (4)	11 Aug 2020 21:54:20

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:54:20

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:54:20

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:04:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:54:20

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:04:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:54:20

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:04:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	11 Aug 2020 21:54:20

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Aug 2020 21:54:20

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 21:54:20

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:04:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:49
User closed query 'Per discharge notes, subject is to cont taking atorvastatin, ambrisentan, enalapril, furosemide, metformin, nebivolol. Please verify if these meds are taken and update records as needed. Thank you! ' (Site from CRA).		09 Apr 2021 18:40:58
Query 'Per discharge notes, subject is to cont taking atorvastatin, ambrisentan, enalapril, furosemide, metformin, nebivolol. Please verify if these meds are taken and update records as needed. Thank you! ' answered with 'all meds are up to date, some are listed as their generic or trade name instead of what is in medical records. thanks!' (Site from CRA).	Cassandra Zehenny (b) (4)	08 Apr 2021 20:31:02
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:29:02
User opened query 'Per discharge notes, subject is to cont taking atorvastatin, ambrisentan, enalapril, furosemide, metformin, nebivolol. Please verify if these meds are taken and update records as needed. Thank you! ' (Site from CRA).		08 Apr 2021 19:53:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: LIRAGLUTIDE, PRODUCTSYNONYM: VICTOZA - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Aug 2020 21:58:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Aug 2020 21:58:25
Data point term sent to Coder	System	11 Aug 2020 21:56:51
User entered 'Victoza'	Mikayla Frye (b) (4)	11 Aug 2020 21:55:59

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:04:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:49
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:29:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:55:59

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:04:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:49
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:29:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Type 2 diabetes'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:55:59

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:04:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:49
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:29:02
User closed query 'Per discharge notes- change of dose to 1.8mg . Please reconcile and update the end date for 0.6mg , start new line for 1.8 mg, as needed. ' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 20:28:52
Query 'Per discharge notes- change of dose to 1.8mg . Please reconcile and update the end date for 0.6mg , start new line for 1.8 mg, as needed. ' answered with 'added, thank you' (Site from CRA).	Cassandra Zehenny (b) (4) (b) (4)	08 Apr 2021 20:27:15
User opened query 'Per discharge notes- change of dose to 1.8mg . Please reconcile and update the end date for 0.6mg , start new line for 1.8 mg, as needed. ' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 19:48:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered '0.6'	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:55:59

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:04:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:49
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:29:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'mg (mg)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:55:59

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:04:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:49
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:29:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:55:59

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:04:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:49
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:29:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'once daily (QD)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:55:59

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:04:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:49
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:29:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:55:59

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:04:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:49
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:29:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:55:59

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:04:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:49
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:29:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:55:59

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:49
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:29:02
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 09:38:51
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Date is correct as entered.' (Site from System).	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:56:21
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 21:55:59
User entered 'UN UNK 1998'	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:55:59

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:49
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:29:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:55:59

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:49
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 20:29:02
Signature has been broken.	Cassandra Zehenny (b) (4)	08 Apr 2021 20:24:36
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Cassandra Zehenny (b) (4)	08 Apr 2021 20:24:36
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
	(b) (4)	
User entered 'Yes (Y)'	Mikayla Frye (b) (4)	11 Aug 2020 21:55:59
	(b) (4)	

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	16 Apr 2021 17:57:24
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:29:02
Signature has been broken.	Cassandra Zehenny (b) (4) (b) (4)	08 Apr 2021 20:24:36
User entered '08 Mar 2021' reason for change: New Information	Cassandra Zehenny (b) (4) (b) (4)	08 Apr 2021 20:24:36
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered empty.	Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:55:59

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:04:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:49
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:29:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	11 Aug 2020 21:55:59

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:04:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:49
User entered 'l'	System	11 Aug 2020 21:55:59

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:49
User entered 'I'	System	11 Aug 2020 21:55:59

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:49
User entered '804 (804)'	System	11 Aug 2020 21:55:59

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:04:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
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)	22 Sep 2020 17:58:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 17:58:47
Data point term sent to Coder	System	22 Sep 2020 17:57:28
User entered 'influenza vaccine'	Stanley Doublin (b) (4)	22 Sep 2020 17:57:06

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:04:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4)	22 Sep 2020 17:57:06

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:04:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:55
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 06:46:23
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.' answered with 'no associated medical condition; seasonal flu shot that everyone is encouraged to receive' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	30 Oct 2020 18:44:20
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 02:08:32
User entered 'Prophylaxis'	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 17:57:06

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:04:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'l'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 17:57:06

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:04:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Other (OTHER)'	(b) (4) Stanley Dublin (b) (4)	22 Sep 2020 17:57:06

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:04:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'cc'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 17:57:06

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:04:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'once (ONCE)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 17:57:06

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:04:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Stanley Dublin (b) (4)	22 Sep 2020 17:57:06

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:04:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:55
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:20:35
User entered 'Intramuscular (INTRAMUSCULAR)'	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 17:57:06

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:04:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Stanley Dublin (b) (4)	22 Sep 2020 17:57:06

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '21 Sep 2020'	(b) (4) Stanley Dublin (b) (4)	22 Sep 2020 17:57:06

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 17:57:06

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 17:57:06

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '21 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 17:57:06

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:04:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4)	22 Sep 2020 17:57:06

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:04:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:55
User entered empty.	System	22 Sep 2020 17:57:06

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:55
User entered empty.	System	22 Sep 2020 17:57:06

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:55
User entered empty.	System	22 Sep 2020 17:57:06

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:04:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Jan 2021 15:45:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Jan 2021 15:45:27
Data point term sent to Coder	System	04 Jan 2021 15:44:47
User entered 'pneumonia vaccine'	Stanley Doublin (b) (4) (b) (4)	04 Jan 2021 15:43:49

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:04:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Jan 2021 15:43:49

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:04:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'pneumonia prophylactic'	(b) (4) Stanley Doublin (b) (4) (b) (4)	04 Jan 2021 15:43:49

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:04:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'l'	(b) (4) Stanley Doublin (b) (4) (b) (4)	04 Jan 2021 15:43:49

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:04:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Other (OTHER)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	04 Jan 2021 15:43:49

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:04:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'injection'	(b) (4) Stanley Doublin (b) (4) (b) (4)	04 Jan 2021 15:43:49

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:04:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4)	
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	04 Jan 2021 15:44:05
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	04 Jan 2021 15:44:05
User entered 'once (ONCE)'	System	04 Jan 2021 15:43:49
	Stanley Dublin (b) (4)	04 Jan 2021 15:43:49
	(b) (4)	

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:04:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Jan 2021 15:43:49

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:04:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Jan 2021 15:43:49

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:04:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Jan 2021 15:43:49

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '05 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Stanley Dublin (b) (4)	04 Jan 2021 15:44:05
User entered '05 UNK 2020'	(b) (4)	
	Stanley Dublin (b) (4)	04 Jan 2021 15:43:49
	(b) (4)	

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	04 Jan 2021 15:43:49

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	04 Jan 2021 15:43:49

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered '05 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Jan 2021 15:43:49

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:04:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	04 Jan 2021 15:43:49

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:04:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:59
User entered empty.	System	04 Jan 2021 15:43:49

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:59
User entered empty.	System	04 Jan 2021 15:43:49

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:39:59
User entered empty.	System	04 Jan 2021 15:43:49

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:04:59

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:20
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: FERROUS SULFATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Mar 2021 18:51:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Mar 2021 18:51:29
Data point term sent to Coder	System	25 Mar 2021 18:50:30
Data point term sent to Coder	System	25 Mar 2021 18:49:30
User entered 'ferrous sulfate'	Heather Douds (b) (4)	25 Mar 2021 18:49:12

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:04:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:20
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:29
Signature has been broken.	(b) (4) Cassandra Zehenny (b) (4)	06 Apr 2021 14:51:11
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Cassandra Zehenny (b) (4)	06 Apr 2021 14:51:11
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 18:49:12

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:04:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:20
User closed query 'Per DM CLR: Please review Con Med if also used for AE#1 SEVERE ANEMIA as the Prophylaxis field is ticked as NO. If associated, kindly ensure to update CM Indication to reflect the medical condition/diagnosis this con med is being used. Otherwise, please clarify.' (Site from DM).		07 Apr 2021 02:27:10
Query 'Per DM CLR: Please review Con Med if also used for AE#1 SEVERE ANEMIA as the Prophylaxis field is ticked as NO. If associated, kindly ensure to update CM Indication to reflect the medical condition/diagnosis this con med is being used. Otherwise, please clarify.' answered with 'health promotion' (Site from DM).	Cassandra Zehenny (b) (4)	06 Apr 2021 14:51:18
User opened query 'Per DM CLR: Please review Con Med if also used for AE#1 SEVERE ANEMIA as the Prophylaxis field is ticked as NO. If associated, kindly ensure to update CM Indication to reflect the medical condition/diagnosis this con med is being used. Otherwise, please clarify.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 11:27:37
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'HEALTH' reason for change: Data Entry Error	Heather Douds (b) (4)	25 Mar 2021 18:49:56
User entered 'health, severe anemia'	Heather Douds (b) (4)	25 Mar 2021 18:49:12

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:04:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:20
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '325'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 18:49:12

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:04:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:20
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'mg (mg)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 18:49:12

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:04:59

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:20
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 18:49:12

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:04:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:20
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'twice daily (BID)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 18:49:12

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:04:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:20
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 18:49:12

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:04:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:20
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Oral (ORAL)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 18:49:12

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:04:59

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:20
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 18:49:12

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:20
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '12 Mar 2021'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 18:49:12

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:20
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 18:49:12

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:20
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 18:49:12

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:20
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 18:49:12

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:04:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:20
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 18:49:12

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:04:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	25 Mar 2021 18:49:12

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Mar 2021 18:49:12

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Mar 2021 18:49:12

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:04:59

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:43:32
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 07:31:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 07:31:45
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
Data point term sent to Coder	(b) (4) System	25 Mar 2021 18:54:34
User entered 'Lidocaine 5%'	Heather Douds (b) (4)	25 Mar 2021 18:54:17
	(b) (4)	

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:04:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:43:32
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 18:54:17

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:04:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:43:32
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'rectal pain'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 18:54:17

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:04:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:43:32
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'l'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 18:54:17

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:04:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:43:32
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Other (OTHER)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 18:54:17

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:04:59

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:43:32
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'application'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 18:54:17

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:04:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:43:32
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'as needed (PRN)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 18:54:17

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:04:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:43:32
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 18:54:17

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:04:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:43:32
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Topical (TOPICAL)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 18:54:17

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:04:59

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:43:32
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 18:54:17

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:43:32
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '12 Mar 2021'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 18:54:17

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:43:32
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 18:54:17

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:43:32
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 18:54:17

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:43:32
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4)	25 Mar 2021 18:54:17

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:04:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:43:32
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 18:54:17

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:04:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 18:54:17

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 18:54:17

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 18:54:17

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:04:59

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:46
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Mar 2021 10:44:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Mar 2021 10:44:50
Data point term sent to Coder	System	25 Mar 2021 19:17:59
User entered 'Pantoprazole'	Heather Douds (b) (4)	25 Mar 2021 19:17:32

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:04:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:46
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:17:32

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:04:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:46
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'chronic gastritis'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:17:32

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:04:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:46
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '40'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:17:32

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:04:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:46
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'mg (mg)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:17:32

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:04:59

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:46
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:17:32

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:04:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:46
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'once daily (QD)'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 19:17:32

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:04:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:46
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:17:32

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:04:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:46
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Oral (ORAL)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:17:32

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:04:59

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:46
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:17:32

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:46
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '12 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:17:32

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:46
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:17:32

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:46
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 19:17:32

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:46
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:17:32

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:04:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:46
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:17:32

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:04:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	25 Mar 2021 19:17:32

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Mar 2021 19:17:32

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Mar 2021 19:17:32

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:04:59

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:55
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 08:38:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 08:38:35
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
Data point term sent to Coder	(b) (4) System	25 Mar 2021 19:18:59
User entered 'Tamsulosin'	Heather Douds (b) (4)	25 Mar 2021 19:18:14
	(b) (4)	

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:04:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:55
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:18:14

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:04:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:55
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'acute renal failure'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:18:14

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:04:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:55
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0.4'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:18:14

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:04:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:55
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'mg (mg)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:18:14

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:04:59

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:55
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:18:14

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:04:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:55
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'once daily (QD)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:18:14

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:04:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:55
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:18:14

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:04:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:55
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Oral (ORAL)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:18:14

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:04:59

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:55
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:18:14

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:55
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '12 Mar 2021'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 19:18:14

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:55
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:18:14

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:55
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 19:18:14

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:55
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:18:14

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:04:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:40:55
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:18:14

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:04:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	25 Mar 2021 19:18:14

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	25 Mar 2021 19:18:14

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Mar 2021 19:18:14

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:04:59

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:35
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 19:19:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 19:19:29
Data point term sent to Coder	System	25 Mar 2021 19:19:00
User entered 'Eliquis'	Heather Douds (b) (4)	25 Mar 2021 19:18:48

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:04:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:35
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:18:48

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:04:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:35
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'atrial fibrillation'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:18:48

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:04:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:35
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '5'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:18:48

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:04:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:35
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'mg (mg)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:18:48

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:04:59

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:35
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:18:48

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:04:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:35
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'twice daily (BID)'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 19:18:48

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:04:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:35
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:18:48

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:04:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:35
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Oral (ORAL)'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 19:18:48

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:04:59

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:35
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:18:48

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 20:28:24
User closed query 'Per source, start date 17Mar2021. Please reconcile ' (Site from CRA).		08 Apr 2021 20:28:23
Query 'Per source, start date 17Mar2021. Please reconcile ' answered with 'updated' (Site from CRA).	Heather Douds (b) (4)	08 Apr 2021 20:09:16
DataPoint Un-verified.	(b) (4)	
	Heather Douds (b) (4)	08 Apr 2021 20:09:11
Signature has been broken.	(b) (4)	
	Heather Douds (b) (4)	08 Apr 2021 20:09:11
User entered '17 Mar 2021' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:35
User opened query 'Per source, start date 17Mar2021. Please reconcile ' (Site from CRA).		08 Apr 2021 19:41:33
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
	(b) (4)	
User entered '12 Mar 2021'	Heather Douds (b) (4)	25 Mar 2021 19:18:48
	(b) (4)	

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:35
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:18:48

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:35
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 19:18:48

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:35
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4)	25 Mar 2021 19:18:48

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:04:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:35
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:18:48

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:04:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	25 Mar 2021 19:18:48

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Mar 2021 19:18:48

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Mar 2021 19:18:48

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:04:59

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:41:58
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Mar 2021 19:20:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 19:20:29
Data point term sent to Coder	System	25 Mar 2021 19:20:01
User entered 'Hydrocodone/acetaminophen'	Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:19:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:04:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:41:58
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 19:19:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:04:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:41:58
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'rectal pain, excision of internal and external hemorrhoids'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:19:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:04:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:41:58
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '5/325'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 19:19:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:04:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:41:58
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'mg (mg)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:19:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:04:59

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:41:58
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4)	25 Mar 2021 19:19:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:04:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:41:58
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'as needed (PRN)'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 19:19:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:04:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:41:58
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4)	25 Mar 2021 19:19:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:04:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:41:58
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Oral (ORAL)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:19:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:04:59

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:41:58
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:19:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:41:58
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '12 Mar 2021'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 19:19:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:41:58
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:19:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:41:58
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 19:19:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:41:58
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4)	25 Mar 2021 19:19:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:04:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:41:58
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 19:19:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:04:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 19:19:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 19:19:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 19:19:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:04:59

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:42:09
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:05:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:05:12
User signature succeeded.	sharon frey (b) (4) (b) (4)	29 Mar 2021 13:55:30
Data point term sent to Coder	System	26 Mar 2021 20:05:11
Data point term sent to Coder	System	25 Mar 2021 19:21:03
User entered 'furosemide'	Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:20:40

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:04:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:42:09
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:20:40

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:04:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:42:09
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'ACUTE HYPOXIC RESPIRATORY FAILURE' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	26 Mar 2021 20:04:52
User entered 'acute hypoxic respiratory failure due to congestive heart failure, hypertension'	(b) (4)	
	Heather Douds (b) (4)	25 Mar 2021 19:20:40
	(b) (4)	

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:04:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:42:09
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '60'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 19:20:40

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:04:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:42:09
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'mg (mg)'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 19:20:40

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:04:59

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:42:09
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:20:40

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:04:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:42:09
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'once daily (QD)'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 19:20:40

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:04:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:42:09
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4)	25 Mar 2021 19:20:40

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:04:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:42:09
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Oral (ORAL)'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 19:20:40

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:04:59

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:42:09
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:20:40

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:42:09
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '12 Mar 2021'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 19:20:40

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:42:09
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:20:40

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:42:09
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 19:20:40

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:42:09
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4)	25 Mar 2021 19:20:40

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:04:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:42:09
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:20:40

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:04:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	25 Mar 2021 19:20:40

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Mar 2021 19:20:40

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Mar 2021 19:20:40

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:04:59

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:29
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	25 Mar 2021 19:27:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 19:27:30
Data point term sent to Coder	System	25 Mar 2021 19:27:19
User entered 'Metformin'	Heather Douds (b) (4)	25 Mar 2021 19:27:04

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:04:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:29
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:27:04

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:04:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:29
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Type II diabetes'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 19:27:04

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:04:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:29
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '500'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:27:04

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:04:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:29
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'mg (mg)'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 19:27:04

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:04:59

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:29
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:27:04

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:04:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:29
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'once daily (QD)'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 19:27:04

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:04:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:29
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4)	25 Mar 2021 19:27:04

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:04:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:29
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Oral (ORAL)'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 19:27:04

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:04:59

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:29
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:27:04

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:29
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '12 Mar 2021'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 19:27:04

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:29
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 19:27:04

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:29
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 19:27:04

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:29
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:27:04

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:04:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:29
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:27:04

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:04:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	25 Mar 2021 19:27:04

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Mar 2021 19:27:04

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Mar 2021 19:27:04

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:04:59

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:42:48
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: OTHER ANTIHYPERTENSIVES, ATC: ANTIHYPERTENSIVES FOR PULMONARY ARTERIAL HYPERTENSION, PRODUCT: TADALAFIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 19:28:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 19:28:30
Data point term sent to Coder	System	25 Mar 2021 19:28:19
User entered 'tadalafil'	Heather Douds (b) (4)	25 Mar 2021 19:27:38

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:04:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:42:48
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:27:38

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:04:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:42:48
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'pulmonary hypertension'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:27:38

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:04:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:42:48
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '40'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:27:38

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:04:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:42:48
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'mg (mg)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:27:38

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:04:59

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:42:48
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:27:38

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:04:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:42:48
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'once daily (QD)'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 19:27:38

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:04:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:42:48
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:27:38

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:04:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:42:48
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Oral (ORAL)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:27:38

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:04:59

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:42:48
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:27:38

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:42:48
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '12 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:27:38

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:42:48
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:27:38

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:42:48
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 19:27:38

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:42:48
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:27:38

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:04:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:42:48
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:27:38

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:04:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	25 Mar 2021 19:27:38

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Mar 2021 19:27:38

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Mar 2021 19:27:38

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:04:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:40:12
User signature succeeded.	sharon frey (b) (4) (b) (4)	16 Apr 2021 17:57:24
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: OTHER BLOOD PRODUCTS, PRODUCT: RED BLOOD CELLS, CONCENTRATED - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 09:18:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 09:18:02
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: OTHER BLOOD PRODUCTS, PRODUCT: BLOOD CELLS, PACKED HUMAN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 09:14:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 09:14:00
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:13
Data point term sent to Coder	System	12 Apr 2021 13:59:33
User closed query 'CDM-Coding: Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term.	System	12 Apr 2021 13:58:50
' (Site from System).		
Query 'CDM-Coding: Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term.	Cassandra Zehenny (b) (4) (b) (4)	12 Apr 2021 13:58:50
' answered with 'updated' (Site from System).		
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	12 Apr 2021 13:58:46
Coding entries removed.	Cassandra Zehenny (b) (4) (b) (4)	12 Apr 2021 13:58:46
Signature has been broken.	Cassandra Zehenny (b) (4) (b) (4)	12 Apr 2021 13:58:46

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US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:04:59

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'BLOOD [packed red blood cells]' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	12 Apr 2021 13:58:46
User opened query 'CDM-Coding: Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term.	Coder Import (b) (4)	12 Apr 2021 05:05:42
' (Site from System). DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:43:16
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: OTHER BLOOD PRODUCTS, PRODUCT: BLOOD, WHOLE, PRODUCTSYNONYM: BLOOD - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 19:29:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 19:29:29
Data point term sent to Coder	System	25 Mar 2021 19:29:20
User entered 'blood'	Heather Douds (b) (4)	25 Mar 2021 19:28:42

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:04:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:40:12
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:43:16
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:28:42

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:04:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:40:12
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:43:16
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'severe anemia, lightheadedness, shortness of breath, fatigue'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:28:42

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:04:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:40:12
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:43:16
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '6'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:28:42

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:04:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:40:12
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:43:16
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Other (OTHER)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:28:42

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:04:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:40:12
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:43:16
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'units'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:28:42

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:04:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:40:12
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:43:16
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'as needed (PRN)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:28:42

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:04:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:40:12
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:43:16
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:28:42

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:04:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:40:12
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:43:16
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:28:42

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:04:59

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:40:12
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:43:16
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:28:42

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:40:12
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:43:16
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '8 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:28:42

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:40:12
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:43:16
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:28:42

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:40:12
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:43:16
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:28:42

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:40:12
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:43:16
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '12 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:28:42

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:04:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:40:12
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:43:16
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:28:42

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:04:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:40:12
User entered empty.	System	25 Mar 2021 19:28:42

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:40:12
User entered empty.	System	25 Mar 2021 19:28:42

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:40:12
User entered empty.	System	25 Mar 2021 19:28:42

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:04:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: LIRAGLUTIDE, PRODUCTSYNONYM: VICTOZA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Apr 2021 20:29:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 20:29:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:29:09
Data point term sent to Coder	System	08 Apr 2021 20:28:42
User entered 'victoza'	Cassandra Zehenny (b) (4) (b) (4)	08 Apr 2021 20:27:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:04:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:29:09
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	08 Apr 2021 20:27:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:04:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:29:09
User entered 'type 2 diabetes'	Cassandra Zehenny (b) (4) (b) (4)	08 Apr 2021 20:27:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:04:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 20:29:09
User entered '1.8'	Cassandra Zehenny (b) (4)	08 Apr 2021 20:27:45
	(b) (4)	

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:04:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 20:29:09
User entered 'mg (mg)'	Cassandra Zehenny (b) (4)	08 Apr 2021 20:27:45
	(b) (4)	

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:04:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 20:29:09
User entered empty.	Cassandra Zehenny (b) (4)	08 Apr 2021 20:27:45
	(b) (4)	

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:04:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 20:29:09
User entered 'once daily (QD)'	Cassandra Zehenny (b) (4)	08 Apr 2021 20:27:45
	(b) (4)	

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:04:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 20:29:09
User entered empty.	Cassandra Zehenny (b) (4)	08 Apr 2021 20:27:45
	(b) (4)	

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:04:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 20:29:09
User entered 'Subcutaneous (SUBCUTANEOUS)'	Cassandra Zehenny (b) (4)	08 Apr 2021 20:27:45
	(b) (4)	

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:04:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 20:29:09
User entered empty.	Cassandra Zehenny (b) (4)	08 Apr 2021 20:27:45
	(b) (4)	

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 20:29:09
User entered '12 Mar 2021'	Cassandra Zehenny (b) (4)	08 Apr 2021 20:27:45
	(b) (4)	

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:04:59

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:24
DataPoint Verified.	(b) (4)	08 Apr 2021 20:29:09
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 20:29:09
	Cassandra Zehenny (b) (4)	08 Apr 2021 20:27:45
	(b) (4)	

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 20:29:09
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	08 Apr 2021 20:27:45
	(b) (4)	

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:04:59

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 20:29:09
User entered empty.	Cassandra Zehenny (b) (4)	08 Apr 2021 20:27:45
	(b) (4)	

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:04:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 20:29:09
User entered 'No (N)'	Cassandra Zehenny (b) (4)	08 Apr 2021 20:27:45
	(b) (4)	

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:04:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	08 Apr 2021 20:27:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	08 Apr 2021 20:27:45

US3552005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:04:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Apr 2021 20:27:45

US3552005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:04:59

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:56:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:31:06
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:26:04
User closed query 'Per ETRTR: According to SAE page "Rectal Bleeding", a Procedure was performed for SAE, but the same is missing in this folder. Please add Concomitant Procedure details for SAE or reconcile otherwise, thanks.' (Site from CRA). Signature has been broken.	(b) (4) (b) (4), (b) (6) Heather Douds (b) (4)	07 Apr 2021 18:04:12 25 Mar 2021 19:03:32
User entered 'Yes (Y)' reason for change: New Information	Heather Douds (b) (4)	25 Mar 2021 19:03:32
Query 'Per ETRTR: According to SAE page "Rectal Bleeding", a Procedure was performed for SAE, but the same is missing in this folder. Please add Concomitant Procedure details for SAE or reconcile otherwise, thanks.' answered with 'awaiting records, will fill out once we have them.' (Site from CRA).	Cassandra Zehenny (b) (4)	24 Mar 2021 16:13:06
User opened query 'Per ETRTR: According to SAE page "Rectal Bleeding", a Procedure was performed for SAE, but the same is missing in this folder. Please add Concomitant Procedure details for SAE or reconcile otherwise, thanks.' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 15:58:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:20:35
User entered 'No (N)'	(b) (4) Heather Douds (b) (4)	17 Feb 2021 21:27:03

US3552005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:04:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:31:34
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '7 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:04:09

US3552005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:04:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:31:34
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'upper GI endoscopy'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:04:09

US3552005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:04:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:31:34
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Adverse Event (AE)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:04:09

US3552005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:04:59

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:31:34
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:04:09

US3552005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:04:59

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:58:32
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:31:35
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '7 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:04:29

US3552005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:04:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:58:32
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:31:35
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'colonoscopy'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:04:29

US3552005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:04:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:58:32
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:31:35
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Adverse Event (AE)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:04:29

US3552005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:04:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:58:32
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:31:35
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:04:29

US3552005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:04:59

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:58:35
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:31:27
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '7 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:04:50

US3552005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:04:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:58:35
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:31:27
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'excision of internal and external hemorrhoids'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:04:50

US3552005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:04:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:58:35
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:31:27
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'Adverse Event (AE)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:04:50

US3552005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:04:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:58:35
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:31:27
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 19:04:50

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered	System	23 Mar 2021 10:07:14
'USA-US089-2021-MRNA-1273-P301000004'		

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'Yes (Y)'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'No (N)'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	23 Mar 2021 10:07:52
User entered 'No (N)'	(b) (4), (b) (6) System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'Yes (Y)'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	23 Mar 2021 10:07:52
User entered 'No (N)'	(b) (4), (b) (6) System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'No (N)'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	23 Mar 2021 10:07:52
User entered 'No (N)'	(b) (4), (b) (6) System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'sharon'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'frey'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:05:46
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
Un-reviewed for Safety.	(b) (4)	26 Mar 2021 14:19:17
User entered empty.	System	26 Mar 2021 14:19:17
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 14:19:03
User entered '1100 S. Grand Blvd'	Heather Douds (b) (4)	25 Mar 2021 16:51:31
	(b) (4)	

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:05:46
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
Un-reviewed for Safety.	(b) (4)	26 Mar 2021 14:19:17
User entered empty.	System	26 Mar 2021 14:19:17
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 14:19:03
User entered 'Saint Louis'	Heather Douds (b) (4)	25 Mar 2021 16:51:31
	(b) (4)	

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	23 Mar 2021 10:07:52
User entered 'MO'	(b) (4), (b) (6)	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:05:46
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
Un-reviewed for Safety.	(b) (4)	26 Mar 2021 14:19:17
User entered empty.	System	26 Mar 2021 14:19:17
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 14:19:03
User entered '63104'	Heather Douds (b) (4)	25 Mar 2021 16:51:31
	(b) (4)	

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 14:19:03
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered 'US'	(b) (4) System	23 Mar 2021 10:08:21

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	09 Apr 2021 13:08:07
User entered '4'	System	06 Apr 2021 13:47:54
User entered '3'	System	01 Apr 2021 14:05:57
User entered '2'	System	26 Mar 2021 14:19:17
User entered '1'	System	23 Mar 2021 10:08:21

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered	System	23 Mar 2021 10:07:14
'USA-US089-2021-MRNA-1273-P301000004'		

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'Yes (Y)'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	23 Mar 2021 10:07:52
User entered 'No (N)'	(b) (4), (b) (6)	23 Mar 2021 10:07:14
	System	

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	23 Mar 2021 10:07:52
User entered 'No (N)'	(b) (4), (b) (6) System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	23 Mar 2021 10:07:52
User entered 'Yes (Y)'	(b) (4), (b) (6) System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	23 Mar 2021 10:07:52
User entered 'No (N)'	(b) (4), (b) (6) System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	23 Mar 2021 10:07:52
User entered 'No (N)'	(b) (4), (b) (6) System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'No (N)'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'sharon'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'frey'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:05:46
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
Un-reviewed for Safety.	(b) (4)	26 Mar 2021 14:19:17
User entered empty.	System	26 Mar 2021 14:19:17
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 14:19:03
User entered '1100 S. Grand Blvd'	Heather Douds (b) (4)	25 Mar 2021 16:51:31
	(b) (4)	

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:05:46
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
Un-reviewed for Safety.	(b) (4)	26 Mar 2021 14:19:17
User entered empty.	System	26 Mar 2021 14:19:17
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 14:19:03
User entered 'Saint Louis'	Heather Douds (b) (4)	25 Mar 2021 16:51:31
	(b) (4)	

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'MO'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:05:46
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	26 Mar 2021 14:19:17
Reviewed for Safety.	System	26 Mar 2021 14:19:17
	(b) (4), (b) (6)	26 Mar 2021 14:19:03
User entered '63104'	Heather Douds (b) (4)	25 Mar 2021 16:51:31
	(b) (4)	

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 14:19:03
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered 'US'	(b) (4) System	23 Mar 2021 10:08:21

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	09 Apr 2021 13:08:07
User entered '4'	System	06 Apr 2021 13:47:54
User entered '3'	System	01 Apr 2021 14:05:57
User entered '2'	System	26 Mar 2021 14:19:17
User entered '1'	System	23 Mar 2021 10:08:21

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:04:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered '23/Mar/2021 10:08'	(b) (4) System	23 Mar 2021 10:08:21

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:04:59

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)	01 Apr 2021 17:01:04
Reviewed for Safety.		26 Mar 2021 14:19:03
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered 'l'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 10:08:21

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'USA-US089-2021-MRNA-1273-P301000004'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'Yes (Y)'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'No (N)'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'No (N)'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'Yes (Y)'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'No (N)'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'No (N)'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'No (N)'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	23 Mar 2021 10:07:52
User entered 'sharon'	(b) (4), (b) (6) System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	23 Mar 2021 10:07:52
User entered 'frey'	(b) (4), (b) (6)	23 Mar 2021 10:07:14
	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:05:46
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
Un-reviewed for Safety.	(b) (4)	26 Mar 2021 14:19:17
User entered empty.	System	26 Mar 2021 14:19:17
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 14:19:03
User entered '1100 S. Grand Blvd'	Heather Douds (b) (4)	25 Mar 2021 16:51:31
	(b) (4)	

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:05:46
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
Un-reviewed for Safety.	(b) (4)	26 Mar 2021 14:19:17
User entered empty.	System	26 Mar 2021 14:19:17
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 14:19:03
User entered 'Saint Louis'	Heather Douds (b) (4)	25 Mar 2021 16:51:31
	(b) (4)	

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	23 Mar 2021 10:07:52
User entered 'MO'	(b) (4), (b) (6)	23 Mar 2021 10:07:14
	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:05:46
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
Un-reviewed for Safety.	(b) (4)	26 Mar 2021 14:19:17
User entered empty.	System	26 Mar 2021 14:19:17
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 14:19:03
User entered '63104'	Heather Douds (b) (4)	25 Mar 2021 16:51:31
	(b) (4)	

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 14:19:03
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered 'US'	(b) (4) System	23 Mar 2021 10:08:21

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	09 Apr 2021 13:08:07
User entered '4'	System	06 Apr 2021 13:47:54
User entered '3'	System	01 Apr 2021 14:05:57
User entered '2'	System	26 Mar 2021 14:19:17
User entered '1'	System	23 Mar 2021 10:08:21

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:04:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered '26/Mar/2021 09:19'	(b) (4) System	26 Mar 2021 14:19:17

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:04:59

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)	01 Apr 2021 17:01:04
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:05:46
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
User entered 'l'	(b) (4), (b) (6)	26 Mar 2021 14:19:17

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'USA-US089-2021-MRNA-1273-P301000004'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'Yes (Y)'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'No (N)'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'No (N)'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'Yes (Y)'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	23 Mar 2021 10:07:52
User entered 'No (N)'	(b) (4), (b) (6)	23 Mar 2021 10:07:14
	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'No (N)'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'No (N)'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'sharon'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	23 Mar 2021 10:07:52
User entered 'frey'	(b) (4), (b) (6) System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:05:46
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
Un-reviewed for Safety.	(b) (4)	26 Mar 2021 14:19:17
User entered empty.	System	26 Mar 2021 14:19:17
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 14:19:03
User entered '1100 S. Grand Blvd'	Heather Douds (b) (4)	25 Mar 2021 16:51:31
	(b) (4)	

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:05:46
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
Un-reviewed for Safety.	(b) (4)	26 Mar 2021 14:19:17
User entered empty.	System	26 Mar 2021 14:19:17
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 14:19:03
User entered 'Saint Louis'	Heather Douds (b) (4)	25 Mar 2021 16:51:31
	(b) (4)	

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'MO'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:05:46
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	26 Mar 2021 14:19:17
Reviewed for Safety.	System	26 Mar 2021 14:19:17
	(b) (4), (b) (6)	26 Mar 2021 14:19:03
User entered '63104'	Heather Douds (b) (4)	25 Mar 2021 16:51:31
	(b) (4)	

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 14:19:03
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered 'US'	(b) (4) System	23 Mar 2021 10:08:21

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	09 Apr 2021 13:08:07
User entered '4'	System	06 Apr 2021 13:47:54
User entered '3'	System	01 Apr 2021 14:05:57
User entered '2'	System	26 Mar 2021 14:19:17
User entered '1'	System	23 Mar 2021 10:08:21

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:04:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:29
DataPoint Verified.	(b) (4)	01 Apr 2021 17:01:04
User entered '01/Apr/2021 09:05'	(b) (4), (b) (6) System	01 Apr 2021 14:05:57

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:04:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:29
Reviewed for Safety.	(b) (4)	06 Apr 2021 13:47:35
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User entered 'l'		01 Apr 2021 14:05:57

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered	System	23 Mar 2021 10:07:14
'USA-US089-2021-MRNA-1273-P301000004'		

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'Yes (Y)'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'No (N)'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'No (N)'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'Yes (Y)'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'No (N)'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'No (N)'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'No (N)'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	23 Mar 2021 10:07:52
User entered 'sharon'	(b) (4), (b) (6) System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	23 Mar 2021 10:07:52
User entered 'frey'	(b) (4), (b) (6)	23 Mar 2021 10:07:14
	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:05:46
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
Un-reviewed for Safety.	(b) (4)	26 Mar 2021 14:19:17
User entered empty.	System	26 Mar 2021 14:19:17
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 14:19:03
User entered '1100 S. Grand Blvd'	Heather Douds (b) (4)	25 Mar 2021 16:51:31
	(b) (4)	

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:05:46
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
Un-reviewed for Safety.	(b) (4)	26 Mar 2021 14:19:17
User entered empty.	System	26 Mar 2021 14:19:17
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 14:19:03
User entered 'Saint Louis'	Heather Douds (b) (4)	25 Mar 2021 16:51:31
	(b) (4)	

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'MO'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:05:46
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
Un-reviewed for Safety.	(b) (4)	26 Mar 2021 14:19:17
User entered empty.	System	26 Mar 2021 14:19:17
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 14:19:03
User entered '63104'	Heather Douds (b) (4)	25 Mar 2021 16:51:31
	(b) (4)	

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 14:19:03
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered 'US'	(b) (4) System	23 Mar 2021 10:08:21

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	09 Apr 2021 13:08:07
User entered '4'	System	06 Apr 2021 13:47:54
User entered '3'	System	01 Apr 2021 14:05:57
User entered '2'	System	26 Mar 2021 14:19:17
User entered '1'	System	23 Mar 2021 10:08:21

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:04:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:04:04
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:29
User entered '06/Apr/2021 09:47'	(b) (4) System	06 Apr 2021 13:47:54

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:04:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:04:04
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:29
User entered 'I'	(b) (4), (b) (6)	06 Apr 2021 13:47:54

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'USA-US089-2021-MRNA-1273-P301000004'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

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Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'Yes (Y)'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'No (N)'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'No (N)'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'Yes (Y)'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	23 Mar 2021 10:07:52
User entered 'No (N)'	(b) (4), (b) (6) System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	23 Mar 2021 10:07:52
User entered 'No (N)'	(b) (4), (b) (6)	23 Mar 2021 10:07:14
	System	

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'No (N)'	System	23 Mar 2021 10:07:14

US3552005

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[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'sharon'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'frey'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

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Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:05:46
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
Un-reviewed for Safety.	(b) (4)	26 Mar 2021 14:19:17
User entered empty.	System	26 Mar 2021 14:19:17
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 14:19:03
User entered '1100 S. Grand Blvd'	Heather Douds (b) (4)	25 Mar 2021 16:51:31
	(b) (4)	

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:05:46
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
Un-reviewed for Safety.	(b) (4)	26 Mar 2021 14:19:17
User entered empty.	System	26 Mar 2021 14:19:17
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 14:19:03
User entered 'Saint Louis'	Heather Douds (b) (4)	25 Mar 2021 16:51:31
	(b) (4)	

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:04:59

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 10:07:52
User entered 'MO'	System	23 Mar 2021 10:07:14

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

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Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:05:46
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:30
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	26 Mar 2021 14:19:17
Reviewed for Safety.	System	26 Mar 2021 14:19:17
	(b) (4), (b) (6)	26 Mar 2021 14:19:03
User entered '63104'	Heather Douds (b) (4)	25 Mar 2021 16:51:31
	(b) (4)	

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:01:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 14:19:03
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:37
User entered 'US'	(b) (4) System	23 Mar 2021 10:08:21

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form

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[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	09 Apr 2021 13:08:07
User entered '4'	System	06 Apr 2021 13:47:54
User entered '3'	System	01 Apr 2021 14:05:57
User entered '2'	System	26 Mar 2021 14:19:17
User entered '1'	System	23 Mar 2021 10:08:21

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:04:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:31:23
User entered '09/Apr/2021 06:08'	System	09 Apr 2021 13:08:07

US3552005

Folder: SAE USA-US089-2021-MRNA-1273-P301000004

Form: Safety Report Form (5)

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Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:31:23
User entered 'I'		09 Apr 2021 13:08:07