

US3812098 (Prod: Sundance Clinical Research - Platinum - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:56:12

All time stamps listed in this document are displayed in GMT

US3812098

Form: Participant Creation

Data signed: (b) (4) 20 Feb 2021 19:41:41

Generated On: 10 Jun 2021 09:56:12

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[Participant ID](#)

US3812098

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

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US3812098

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

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

Visit date (dd MMM yyyy)	10 AUG 2020
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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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US3812098

Folder: Screening

Form: Demographics

Data signed: (b) (4) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

Date of Birth (MMM yyyy)	(b) (6) 1953
Age	67
Age Units	YEARS
Age (Derived)	67
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False



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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 20 Feb 2021 19:41:43

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	10 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input 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) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Mar 2021 19:46:57

Generated On: 10 Jun 2021 09:56:12

Condition	VASECTOMY
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Mar 2021 19:46:57

Generated On: 10 Jun 2021 09:56:12

Condition	(R) INGUINAL HERNIA
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2009
Stop Year (derived)	2009

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Mar 2021 19:46:57

Generated On: 10 Jun 2021 09:56:12

Condition	(R) INGUINAL HERNIA REPAIR
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2009
Stop Year (derived)	2009

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Mar 2021 19:46:57

Generated On: 10 Jun 2021 09:56:12

Condition	CRANIOFACIAL SEPARATION
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 (5)

Data signed: (b) (4) 26 Mar 2021 19:46:57

Generated On: 10 Jun 2021 09:56:12

Condition	CRANIOFACIAL RECONSTRUCTION
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 (6)

Data signed: (b) (4) 26 Mar 2021 19:46:57

Generated On: 10 Jun 2021 09:56:12

Condition	ANOSMIA
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 (7)

Data signed: (b) (4) 26 Mar 2021 19:46:57

Generated On: 10 Jun 2021 09:56:12

Condition	DEPENDENCY OF RIGHT EYE PROSTHETIC
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 (8)

Data signed: (b) (4) 26 Mar 2021 19:46:57

Generated On: 10 Jun 2021 09:56:12

Condition	HISTORY OF MOTOR VEHICLE ACCIDENT
Start date (dd MMM yyyy)	03 NOV 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)	03 NOV 1985
Stop date completely unknown	False
Start Month and Year (derived)	NOV 1985
Start Year (derived)	1985
Stop Month and Year (derived)	NOV 1985
Stop Year (derived)	1985

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 26 Mar 2021 19:46:57

Generated On: 10 Jun 2021 09:56:12

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

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 26 Mar 2021 19:46:57

Generated On: 10 Jun 2021 09:56:12

Condition	SHRIMP ALLERGY
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 26 Mar 2021 19:46:57

Generated On: 10 Jun 2021 09:56:12

Condition	SULFA ALLERGY
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 26 Mar 2021 19:46:57

Generated On: 10 Jun 2021 09:56:12

Condition	ALCOHOL USE-16 OZ OF WINE/DAY
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) 26 Mar 2021 19:46:57

Generated On: 10 Jun 2021 09:56:12

Condition	ANXIETY
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 (14)

Data signed: (b) (4) 26 Mar 2021 19:46:57

Generated On: 10 Jun 2021 09:56:12

Condition	VITAMIN B12-DEFICIENCY
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 26 Mar 2021 19:46:57

Generated On: 10 Jun 2021 09:56:12

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

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 26 Mar 2021 19:46:57

Generated On: 10 Jun 2021 09:56:12

Condition	THYROID NODULES
Start date (dd MMM yyyy)	09 MAR 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 26 Mar 2021 19:46:57

Generated On: 10 Jun 2021 09:56:12

Condition	GLOBUS SENSATION
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	10 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	08:07 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 08:07
Height ( <i>xxx.x</i> )	68.7 in
Weight ( <i>xxx.x</i> )	162.6 lb
BMI ( <i>xxx.x</i> )	24.27264 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	ND - Not Done
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 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) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

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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 ☐

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**Specify** BABYSITS

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**Location and Living Circumstances Risk (check all that apply)**

**No Risk Identified** True

**Resides in Nursing Home or Assisted Living Facility** False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Feb 2021 19:41:43

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



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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

What was the date of randomization? (dd MMM yyyy) 10 AUG 2020

What was the participant's randomization number? 185352

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

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) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

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)	10 AUG 2020
Time of assessment (00:00-23:59)	08:07 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 08:07
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

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)	10 AUG 2020
Time of assessment (00:00-23:59)	10:19 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 10:19
Temperature (xxx.x)	97.9 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)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

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) 20 Feb 2021 19:41:43

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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) 10 AUG 2020

What was the treatment time? (00:00-23:59) 09:47 (24 HR)

Treatment Date and Time (derived) 10 AUG 2020 09:47

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) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 AUG 2020
Collection time (00:00-23:59)	09:20 (24 HR)
Collection date and time (derived)	10 AUG 2020 09:20



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

Collection date (dd MMM yyyy)			10 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:25	10 AUG 2020 09:25
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

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 09:56:12

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 10:24

PC Open Date & Time

10 AUG 2020 10:07

PC Close Date & Time

10 AUG 2020 12:37

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

**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 99.5 °F

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

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

PC Time Stamp	10 AUG 2020 17:58
PC Open Date & Time	10 AUG 2020 13:32
PC Close Date & Time	11 AUG 2020 11:59

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:56:12

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**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

98.4 °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 16:58

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.4 °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 AUG 2020 16:39

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:56:12

**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

98.5 °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

13 AUG 2020 15:14

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 15:52

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59



US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:56:12

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**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

98.6 °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

15 AUG 2020 18:41

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

16 AUG 2020 19:07

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 10:25

PC Open Date & Time

10 AUG 2020 10:07

PC Close Date & Time

10 AUG 2020 12:37

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

**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

10 AUG 2020 18:00

PC Open Date & Time

10 AUG 2020 13:32

PC Close Date & Time

11 AUG 2020 11:59

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:56:12

**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

11 AUG 2020 16:59

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:56:12

**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

12 AUG 2020 16:40

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:56:12

**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

13 AUG 2020 15:14

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:56:12

**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

14 AUG 2020 15:52

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59



US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:56:12

**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

15 AUG 2020 18:41

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:56:12

**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

16 AUG 2020 19:08

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

**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 ☐

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 10:27
PC Open Date & Time	10 AUG 2020 10:07
PC Close Date & Time	10 AUG 2020 12:37

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

**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 ☐

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 18:01
PC Open Date & Time	10 AUG 2020 13:32
PC Close Date & Time	11 AUG 2020 11:59

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:12

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)

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:12

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



US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:12

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

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EAB) (1725)

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:12

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 16:41
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:12

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

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EAB) (1725)

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:12

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 15:15
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:12

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 ☒

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:12

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 15:53
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:12

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)

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US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:12

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 18:42
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59



US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:12

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:12

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 19:08
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3812098

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812098

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812098

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

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*

US3812098

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812098

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812098

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3812098

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

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)	10 SEP 2020
Time of assessment (00:00-23:59)	08:08 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 08:08
Temperature (xxx.x)	97.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

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)	10 SEP 2020
Time of assessment (00:00-23:59)	09:08 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 09:08
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3812098

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

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.*

US3812098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

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) 10 SEP 2020

What was the treatment time? (00:00-23:59) 08:37 (24 HR)

Treatment Date and Time (derived) 10 SEP 2020 08:37

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

US3812098

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 SEP 2020
Collection time (00:00-23:59)	08:24 (24 HR)
Collection date and time (derived)	10 SEP 2020 08:24

US3812098

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:27	10 SEP 2020 08:27
Nasopharyngeal Swab 2	No		

US3812098

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

10 SEP 2020 09:12

PC Open Date & Time

10 SEP 2020 08:57

PC Close Date & Time

10 SEP 2020 11:27

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

**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 99.8 °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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 10 SEP 2020 17:02

PC Open Date & Time 10 SEP 2020 12:22

PC Close Date & Time 11 SEP 2020 11:59

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:56:12

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.1 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	11 SEP 2020 15:13
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:56:12

**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 SEP 2020 10:08

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:56:12

**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

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 14:42

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:56:12

**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

14 SEP 2020 18:20

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 18:38

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 17:50

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59



US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 09:13

PC Open Date & Time

10 SEP 2020 08:57

PC Close Date & Time

10 SEP 2020 11:27

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

**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

10 SEP 2020 17:04

PC Open Date & Time

10 SEP 2020 12:22

PC Close Date & Time

11 SEP 2020 11:59

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:56:12

**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

11 SEP 2020 15:14

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:56:12

**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 SEP 2020 10:09

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:56:12

**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

13 SEP 2020 14:42

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:56:12

**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

14 SEP 2020 18:21

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:56:12

**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

15 SEP 2020 18:39

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:56:12

**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

16 SEP 2020 17:50

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59



US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

**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 ☐

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 09:14
PC Open Date & Time	10 SEP 2020 08:57
PC Close Date & Time	10 SEP 2020 11:27

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

**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 ☐

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 17:05
PC Open Date & Time	10 SEP 2020 12:22
PC Close Date & Time	11 SEP 2020 11:59

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:12

**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

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EAB) (1725)

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:12

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

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:12

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

106 of 2764

EAB) (1725)

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:12

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 10:09
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59



US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:12

**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 ☒

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:12

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 14:43
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:12

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

110 of 2764

EAB) (1725)

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:12

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 18:21
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:12

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 ☒

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:12

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 18:40
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:12

**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 ☒

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US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:12

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 17:51
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59



US3812098

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812098

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812098

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812098

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812098

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812098

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812098

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 19:42:00

Generated On: 10 Jun 2021 09:56:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 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

US3812098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 19:42:00

Generated On: 10 Jun 2021 09:56:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	09 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	09:50 (24 HR)
Vital Signs Date and Time (derived)	09 OCT 2020 09:50
Temperature ( <i>xxx.x</i> )	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	76 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3812098

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 19:42:00

Generated On: 10 Jun 2021 09:56:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 OCT 2020

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

US3812098

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 19:42:00

Generated On: 10 Jun 2021 09:56:12

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	09 OCT 2020
Collection time (00:00-23:59)	10:20 (24 HR)
Collection date and time (derived)	09 OCT 2020 10:20

US3812098

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

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 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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	14 OCT 2020 08:44:39
Patient Cloud Open Date & Time	10 OCT 2020 00:01
Patient Cloud Close Date & Time	14 OCT 2020 23:59

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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

20 OCT 2020 12:13:29

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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

27 OCT 2020 07:26:57

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 08:14:43

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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

17 NOV 2020 12:54:55

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59



US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

DAY 103

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

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18 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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22 NOV 2020 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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

25 NOV 2020 06:43:20

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

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 <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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	02 DEC 2020 17:32:58
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 DEC 2020 15:40:22

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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

16 DEC 2020 07:50:42

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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

23 DEC 2020 07:50:29

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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

30 DEC 2020 07:09:42

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59



US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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

06 JAN 2021 09:07:10

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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

13 JAN 2021 07:20:12

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 JAN 2021 08:11:29

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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

27 JAN 2021 08:09:45

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 FEB 2021 05:46:04

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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

10 FEB 2021 07:59:51

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 FEB 2021 05:55:13
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 FEB 2021 14:16:56

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59



US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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

03 MAR 2021 09:08:29

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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

10 MAR 2021 07:32:55

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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

17 MAR 2021 10:58:50

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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

24 MAR 2021 06:18:45

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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

31 MAR 2021 08:56:39

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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 19:13:47

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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

14 APR 2021 07:46:06

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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

21 APR 2021 16:27:35

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59



US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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

28 APR 2021 07:06:35

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

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05 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAY 2021 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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 ☐

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

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12 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAY 2021 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

DAY 285

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

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26 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAY 2021 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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 ☐

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

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02 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 JUN 2021 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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 ☐

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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 ☐

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

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"/>



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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 ☐

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 JUL 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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 ☐

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	07 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 JUL 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

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"/>

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

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14 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 JUL 2021 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

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21 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 JUL 2021 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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 ☐

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

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28 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 AUG 2021 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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 ☐

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

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04 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 AUG 2021 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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 ☐

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	11 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	15 AUG 2021 23:59
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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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 ☐



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 AUG 2021 23:59
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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

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



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

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"/>

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

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

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

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

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29 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 OCT 2021 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	06 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	10 OCT 2021 23:59
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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

13 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

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"/>

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 OCT 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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 ☐

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

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03 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 NOV 2021 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

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"/>



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	10 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	14 NOV 2021 23:59
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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

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 <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"/>

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

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17 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 NOV 2021 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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 ☐

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

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24 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 NOV 2021 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

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01 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 DEC 2021 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

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"/>



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

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08 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 DEC 2021 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

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 <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"/>

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 DEC 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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 ☐

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

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22 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 DEC 2021 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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 ☐

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

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29 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 JAN 2022 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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 ☐



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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 ☐

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

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19 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 JAN 2022 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

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

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

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

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

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26 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 JAN 2022 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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 ☐

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

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09 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 FEB 2022 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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 ☐

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

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16 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 FEB 2022 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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 ☐

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	23 FEB 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	27 FEB 2022 23:59
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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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 ☐



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

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02 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 MAR 2022 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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 ☐

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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 ☐

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

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16 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAR 2022 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

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23 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAR 2022 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

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"/>



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

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30 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 APR 2022 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

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"/>

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

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06 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 APR 2022 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

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

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 APR 2022 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

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"/>

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	20 APR 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 APR 2022 23:59
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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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 ☐



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

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27 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 MAY 2022 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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 ☐

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

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04 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 MAY 2022 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

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18 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 MAY 2022 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

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 <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"/>



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

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25 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 MAY 2022 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

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 <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"/>

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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 ☐

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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 ☐

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

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

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

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29 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 JUL 2022 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

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 <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"/>

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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 ☐

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

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13 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 JUL 2022 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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 ☐



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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 ☐

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

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 <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"/>

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

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03 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 AUG 2022 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

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 <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"/>

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

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10 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 AUG 2022 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

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"/>



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	17 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	21 AUG 2022 23:59
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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	24 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	28 AUG 2022 23:59
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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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 ☐

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

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31 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 SEP 2022 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

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"/>

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

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07 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 SEP 2022 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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 ☐



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

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14 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 SEP 2022 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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 ☐

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

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21 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 SEP 2022 23:59

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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 ☐

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**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 ☐

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	05 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	09 OCT 2022 23:59
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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

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 <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"/>



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

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

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[Patient Cloud Open Date & Time](#)

12 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 OCT 2022 23:59

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US3812098

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:56:12

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		03 MAR 2021 09:08:47

US3812098

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812098

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812098

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812098

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812098

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812098

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:41:43

Generated On: 10 Jun 2021 09:56:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3812098

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 19:46:57

Generated On: 10 Jun 2021 09:56:12

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 08 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3812098

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 19:46:57

Generated On: 10 Jun 2021 09:56:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812098

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 19:46:57

Generated On: 10 Jun 2021 09:56:12

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

Visit date (dd MMM yyyy)	04 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3812098

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 MAR 2021
Time of assessment (00:00-23:59)	11:40 (24 HR)
Vital Signs Date and Time (derived)	04 MAR 2021 11:40
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812098

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 19:46:57

Generated On: 10 Jun 2021 09:56:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 MAR 2021

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

US3812098

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 19:46:57

Generated On: 10 Jun 2021 09:56:12

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

04 MAR 2021

Collection time (00:00-23:59)

12:00 (24 HR)

Collection date and time (derived)

04 MAR 2021 12:00

US3812098

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 19:46:57

Generated On: 10 Jun 2021 09:56:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812098

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 5 APR 2021

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

Comments

*If Contact Not Made, please provide Comments*



US3812098

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812098

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:12

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*

**US3812098**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:56:12**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3812098

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:56:12

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

US3812098

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 20 Feb 2021 19:41:42

Generated On: 10 Jun 2021 09:56:12

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[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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US3812098

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

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 19:41:42

Generated On: 10 Jun 2021 09:56:12

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

Visit date (dd MMM yyyy)	08 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3812098

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

Form: Unblinding

Data signed: (b) (4) 26 Mar 2021 19:46:57

Generated On: 10 Jun 2021 09:56:12

Date of updated informed consent (dd MMM yyyy) 08 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 08 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_

US3812098

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 19:41:42

Generated On: 10 Jun 2021 09:56:12

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	08 JAN 2021
Collection time (00:00-23:59)	12:00 (24 HR)
Collection date and time (derived)	08 JAN 2021 12:00



US3812098

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 20 Feb 2021 19:41:42

Generated On: 10 Jun 2021 09:56:12

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	08 JAN 2021
Collection time (00:00 - 23:59)	12:05
Collection Date and Time (derived)	08 JAN 2021 12:05

US3812098

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 20 Feb 2021 19:41:41

Generated On: 10 Jun 2021 09:56:12

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Did the participant experience any adverse events?

Yes ☒  
No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3812098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:56:12

AEID	USA-US111-2020-MRNA-1273-P30 1000005
Adverse event	PROSTATE CANCER
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)	28 AUG 2020
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 type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input 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	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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EAB) (1725)

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US3812098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:56:12

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input 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	

US3812098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:56:12

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THIS IS A 67-YEAR-OLD MALE  
WITH A HISTORY OF  
VASECTOMY, RIGHT INGUINAL  
HERNIA WITH  
REPAIR, DAILY ALCOHOL USE,  
ANXIETY, VITAMIN B12  
DEFICIENCY, THYROID  
NODULES, AND  
MICROALBUMINURIA. HE WAS  
INITIALLY DIAGNOSED WITH  
STAGE T1C PROSTATE CANCER  
IN  
OCTOBER 2020 AFTER A RISING  
PSA. HIS PROSTATE BIOPSY  
SHOWED GLEASON SCORE 7-  
ADENOCARCINOMA AND HIS  
MOST RECENT PSA WAS 7.4 IN  
DECEMBER 2020. HE  
COMPLETED  
A CT PET ON 17NOV2020 DUE  
TO COMPLAINTS OF LUMBAR  
PAIN. THE FINAL REPORT  
SHOWED  
WIDESPREAD MARROW  
ACTIVITY OF LYTIC LESIONS  
THROUGHOUT THE AXIAL AND  
APPENDICULAR  
SKELETON. THE SUBJECT WAS  
DIAGNOSED WITH MULTIPLE  
MYELOMA ON 24NOV2020.  
SUBJECT COMPLETED A  
PERIPHERAL BLOOD SMEAR  
AND A BONE MARROW  
ASPIRATE AND BIOPSY  
ON 02DEC2020. SUBJECT WAS  
CONCLUSIVE FOR  
MACROCYTIC ANEMIA

US3812098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:56:12

---

AND PLASMA CELL  
MYELOMA. SUBJECT WAS  
GIVEN TRAMADOL 100MG Q 6  
HOURS PRN FOR PAIN  
CONTROL.  
LUPRON 25 MG DAILY WAS  
STARTED FOR HIS PROSTATE  
CANCER ON 04DEC2020. HIS  
RECOMMENDED  
CHEMOTHERAPY INCLUDED  
VELCADE SQ WEEKLY,  
REVLIMID 25MG PO DAILY  
DAYS 1-14 EVERY 21 DAYS,  
AND DEXAMETHASONE 20MG  
PO DAY OF AND DAY AFTER  
VELCADE  
INJECTION PRESCRIBED ON  
08DEC2020. VELCADE DOSE IS  
NOT SPECIFIED IN MEDICAL  
RECORDS. ASPIRIN 81MG  
DAILY, COMPAZINE 10MG Q 6  
HOURS PRN, AND PEPCID 20MG  
DAILY ALSO PRESCRIBED ON  
08DEC2020. MONTHLY XGEVA  
120MG SQ WAS ALSO STARTED  
08DEC2020. RADIATION IS ALSO  
BEING CONSIDERED FOR  
PROSTATE CANCER, RATHER  
THAN  
PROSTATECTOMY, DUE TO  
TREATMENT FOR MULTIPLE  
MYELOMA. DURING 22DEC2020  
VISIT, HE  
WAS STARTED ON LIDODERM  
5% PATCH TO AFFECTED AREA  
DAILY FOR ADDITIONAL PAIN

US3812098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:56:12

---

CONTROL.  
HE WAS ALSO STARTED ON  
LEXAPRO 10MG DAILY DURING  
THIS VISIT FOR WORSENING  
ANXIETY.  
LAST REPORTED VISIT WAS  
05JAN2021, WHICH CONTINUES  
THE ESTABLISHED PLAN OF  
CARE.  
WE WILL CONTINUE TO  
FOLLOW THE SAFETY AND  
OUTCOME OF THIS SUBJECT.

---

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)	

---

US3812098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:12

AEID	
Adverse event	BILATERAL HIP PAIN
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	24 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	11 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input 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	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:12

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)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:56:12

AEID	
Adverse event	NECK PAIN
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	22 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	30 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input 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	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:56:12

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)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:12

AEID	
Adverse event	WORSENING LEFT CATARACT
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)	15 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	15 OCT 2020
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	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:12

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	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 (5)

Generated On: 10 Jun 2021 09:56:12

AEID	USA-US111-2020-MRNA-1273-P30 1000020
Adverse event	MULTIPLE MYELOMA
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)	24 NOV 2020
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 type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input 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	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)

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
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 checked="" type="radio"/> Recovered/Resolved <input 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	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:56:12

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THIS IS A 67-YEAR-OLD MALE  
WITH A HISTORY OF  
VASECTOMY, RIGHT INGUINAL  
HERNIA WITH REPAIR, DAILY  
ALCOHOL USE, ANXIETY,  
VITAMIN B12 DEFICIENCY,  
THYROID NODULES, AND  
MICROALBUMINURIA. HE WAS  
INITIALLY DIAGNOSED WITH  
STAGE T1C PROSTATE CANCER  
IN OCTOBER 2020 AFTER A  
RISING PSA. HIS PROSTATE  
BIOPSY SHOWED GLEASON  
SCORE 7- ADENOCARCINOMA  
AND HIS MOST RECENT PSA  
WAS 7.4 IN DECEMBER 2020. HE  
COMPLETED A CT PET ON  
17NOV2020 DUE TO  
COMPLAINTS OF LUMBAR  
PAIN. THE FINAL REPORT  
SHOWED WIDESPREAD  
MARROW ACTIVITY OF LYTIC  
LESIONS THROUGHOUT THE  
AXIAL AND APPENDICULAR  
SKELETON. THE SUBJECT WAS  
DIAGNOSED WITH MULTIPLE  
MYELOMA ON 24NOV2020.  
SUBJECT COMPLETED A  
PERIPHERAL BLOOD SMEAR  
AND A BONE MARROW  
ASPIRATE AND BIOPSY ON  
02DEC2020. SUBJECT WAS  
CONCLUSIVE FOR  
MACROCYTIC ANEMIA AND  
PLASMA CELL MYELOMA.  
SUBJECT WAS GIVEN  
TRAMADOL 100MG Q 6 HOURS



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:56:12

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PRN FOR PAIN CONTROL.  
LUPRON 25 MG DAILY WAS  
STARTED FOR HIS PROSTATE  
CANCER ON 04DEC2020. HIS  
RECOMMENDED  
CHEMOTHERAPY INCLUDED  
VELCADE SQ WEEKLY,  
REVLIMID 25MG PO DAILY  
DAYS 1-14 EVERY 21 DAYS,  
AND DEXAMETHASONE 20MG  
PO DAY OF AND DAY AFTER  
VELCADE INJECTION  
PRESCRIBED ON 08DEC2020.  
VELCADE DOSE IS NOT  
SPECIFIED IN MEDICAL  
RECORDS. ASPIRIN 81MG  
DAILY, COMPAZINE 10MG Q 6  
HOURS PRN, AND PEPCID 20MG  
DAILY ALSO PRESCRIBED ON  
08DEC2020. MONTHLY XGEVA  
120MG SQ WAS ALSO STARTED  
08DEC2020. RADIATION IS ALSO  
BEING CONSIDERED FOR  
PROSTATE CANCER, RATHER  
THAN PROSTATECTOMY, DUE  
TO TREATMENT FOR MULTIPLE  
MYELOMA. DURING 22DEC2020  
VISIT, HE WAS STARTED ON  
LIDODERM 5% PATCH TO  
AFFECTED AREA DAILY FOR  
ADDITIONAL PAIN CONTROL.  
HE WAS ALSO STARTED ON  
LEXAPRO 10MG DAILY DURING  
THIS VISIT FOR WORSENING  
ANXIETY. LAST REPORTED  
VISIT WAS 05JAN2021, WHICH  
CONTINUES THE ESTABLISHED

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:56:12

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PLAN OF CARE. WE WILL  
CONTINUE TO FOLLOW THE  
SAFETY AND OUTCOME OF  
THIS SUBJECT. [06 APR 2021]  
SUBJECT WAS ADMITTED ON  
MARCH 31ST FOR A "STEM  
CELL TRANSPLANT" TO TREAT  
HIS MULTIPLE MYELOMA. THIS  
WAS A PLANNED EVENT AND  
HE IS ANTICIPATED TO BE  
DISCHARGED ON APRIL 15TH.

---

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)	
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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:56:12

AEID	
Adverse event	WORSENING ANXIETY
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)	05 JAN 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)	05 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:56:12

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) _____	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 20 Feb 2021 19:41:42

Generated On: 10 Jun 2021 09:56:12

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

Yes ☒

No ☐

---

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

---

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

Name of Medication COENZYME Q10

Prophylaxis Yes ☒  
No ☐

Indication GENERAL HEALTH

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

	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 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

Name of Medication CEFTRIAXONE

Prophylaxis Yes ☒  
No ☐

Indication PROSTATE BIOPSY

Dose per administration 2.4

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

	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)	02 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy) 02 OCT 2020		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication PAIN AT INJECTION SITE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

	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)		10 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 11 SEP 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication BILATERAL HIP PAIN AND  
NECK PAIN

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

	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)	24 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 01:27:46

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Name of Medication ASPIRIN

Prophylaxis Yes ☐  
No ☒

Indication BILATERAL HIP PAIN AND  
NECK PAIN

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

	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)	24 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

Name of Medication PREDNISONE

Prophylaxis Yes ☐  
No ☒

Indication BILATERAL HIP PAIN

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 (6)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

	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)	04 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	13 NOV 2020	
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 (7)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

Name of Medication PNEUMOVAX

Prophylaxis Yes ☒  
No ☐

Indication IMMUNIZATION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

	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)		04 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		04 NOV 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 (8)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

Name of Medication VITAMIN B-12

Prophylaxis Yes ☐  
No ☒

Indication B-12 DEFICIENCY

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

	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 2019	
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) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

Name of Medication LEHALIDOMIDE

Prophylaxis Yes ☐  
No ☒

Indication PROSTATE CANCER

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 (9)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

	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)	04 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		08 DEC 2020
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) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐  
No ☒

Indication MULTIPLE MYELOMA

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

TWICE A WEEK

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

	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)		08 DEC 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)		_____
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 (11)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

Name of Medication LENALIDOMIDE

Prophylaxis Yes ☐  
No ☒

Indication MULTIPLE MYELOMA

Dose per administration UNK

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

If dose unit is Other, specify UNK

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

	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)		08 DEC 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 checked="" 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) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

Name of Medication ACYCLOVIR

Prophylaxis Yes ☐  
No ☒

Indication MULTIPLE MYELOMA

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

	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)		08 DEC 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)		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 (13)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

Name of Medication NORCO

Prophylaxis Yes ☐  
No ☒

Indication MULTIPLE MYELOMA

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 ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

	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)		08 DEC 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)		_____
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 (14)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

Name of Medication ASPRIN

Prophylaxis Yes ☐  
No ☒

Indication MULTIPLE MYELOMA

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

	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)		08 DEC 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 (16)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

Name of Medication PROCHLORPERAZINE

Prophylaxis Yes ☐  
No ☒

Indication MULTIPLE MYELOMA

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 (16)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

	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)		08 DEC 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)		_____
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 (17)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

Name of Medication ZANAFLEX

Prophylaxis Yes ☐  
No ☒

Indication MULTIPLE MYELOMA

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 8 HOURS AS NEEDED

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

	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)	20 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 02 DEC 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

Name of Medication CANNABIDIOL CBD

Prophylaxis Yes ☐  
No ☒

Indication PROSTATE CANCER AND  
MULTIPLE MYELOMA

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN OCT 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 (19)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

Name of Medication VITAMIN D3

Prophylaxis Yes ☐  
No ☒

Indication PROSTATE CANCER AND  
MULTIPLE MYELOMA

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

4-5 TIMES PER WEEK

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	04 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

Name of Medication VITAMIN C

Prophylaxis Yes ☐  
No ☒

Indication PROSTATE CANCER AND  
MULTIPLE MYELOMA

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

4-5 TIMES PER WEEK

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		04 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

Name of Medication FISH OIL

Prophylaxis Yes ☐  
No ☒

Indication PROSTATE CANCER AND  
MULTIPLE MYELOMA

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

4-5 TIMES PER WEEK

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN OCT 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)		
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 (22)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

Name of Medication TRAMADOL

Prophylaxis Yes ☐  
No ☒

Indication MULTIPLE MYELOMA

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 6 HOURS AS NEEDED

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

	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)		02 DEC 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)		_____
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 (23)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

Name of Medication VELCADE

Prophylaxis Yes ☐  
No ☒

Indication MULTIPLE MYELOMA

Dose per administration UNK

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

If dose unit is Other, specify UNK

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 (23)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

	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)		08 DEC 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 checked="" type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

Name of Medication REVLMID

Prophylaxis Yes ☐  
No ☒

Indication MULTIPLE MYELOMA

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

DAILY DAYS 1-14 EVERY 21  
DAYS

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

	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)		08 DEC 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)		_____
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 (25)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

Name of Medication PEPCID

Prophylaxis Yes ☐  
No ☒

Indication MULTIPLE MYELOMA

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 (25)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

	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)	08 DEC 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 (26)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

Name of Medication XGEVA

Prophylaxis Yes ☐  
No ☒

Indication MULTIPLE MYELOMA

Dose per administration 120

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 (26)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

	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)		08 DEC 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 checked="" type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

Name of Medication LIDODERM 5%

Prophylaxis Yes ☐  
No ☒

Indication MULTIPLE MYELOMA

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 DAILY AS NEEDED

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

PRODUCTION RELEASE (v12.003

403 of 2764

EAB) (1725)



US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

	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)	22 DEC 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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

Name of Medication LEXAPRO

Prophylaxis Yes ☐  
No ☒

Indication WORSENING ANXIETY

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 ☐

PRODUCTION RELEASE (v12.003

405 of 2764

EAB) (1725)

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

	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)	05 JAN 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"/>

US3812098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 20 Feb 2021 19:41:42

Generated On: 10 Jun 2021 09:56:12

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3812098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 08 Apr 2021 01:27:46

Generated On: 10 Jun 2021 09:56:12

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
02 OCT 2020	BIOPSY OF PROSTATE	Adverse Event	
15 OCT 2020	LEFT CATARACT REMOVAL	Adverse Event	
17 NOV 2020	CT PET SCAN	Adverse Event	
2 DEC 2020	PERIPHERAL BLOOD SMEAR	Adverse Event	
02 DEC 2020	BONE MARROW ASPIRATE	Adverse Event	
31 MAR 2021	STEM CELL TRANSPLANT	Adverse Event	

US3812098

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:56:12

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

US3812098

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:56:12

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 ☐

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 08 Apr 2021 16:26:13

Generated On: 10 Jun 2021 09:56:12

SAEID	USA-US111-2020-MRNA-1273-P301000005
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6



US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 08 Apr 2021 16:26:13

Generated On: 10 Jun 2021 09:56:12

SAEID	USA-US111-2020-MRNA-1273-P301000005
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	15/OCT/2020 12:47
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

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 08 Apr 2021 16:26:13

Generated On: 10 Jun 2021 09:56:12

SAEID	USA-US111-2020-MRNA-1273-P301000005
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	22/OCT/2020 20:21
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

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 08 Apr 2021 16:26:13

Generated On: 10 Jun 2021 09:56:12

SAEID	USA-US111-2020-MRNA-1273-P301000005
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	06/NOV/2020 20:27
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

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) 08 Apr 2021 16:26:13

Generated On: 10 Jun 2021 09:56:12

SAEID	USA-US111-2020-MRNA-1273-P301000005
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	16/NOV/2020 09:29
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

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Data signed: (b) (4) 08 Apr 2021 16:26:13

Generated On: 10 Jun 2021 09:56:12

SAEID	USA-US111-2020-MRNA-1273-P301000005
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	16/FEB/2021 12:44
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Data signed: (b) (4) 08 Apr 2021 16:26:13

Generated On: 10 Jun 2021 09:56:12

SAEID	USA-US111-2020-MRNA-1273-P301000005
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	08/APR/2021 07:38
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Data signed: (b) (4) 08 Apr 2021 16:26:13

Generated On: 10 Jun 2021 09:56:12

SAEID	USA-US111-2020-MRNA-1273-P301000020
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form (1)

Data signed: (b) (4) 08 Apr 2021 16:26:13

Generated On: 10 Jun 2021 09:56:12

SAEID	USA-US111-2020-MRNA-1273-P301000020
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LAUREN
Investigator's Last Name	CLEMENT
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/DEC/2020 15:26
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



US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form (2)

Data signed: (b) (4) 08 Apr 2021 16:26:13

Generated On: 10 Jun 2021 09:56:12

SAEID	USA-US111-2020-MRNA-1273-P301000020
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LAUREN
Investigator's Last Name	CLEMENT
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)	07/JAN/2021 14:46
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

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form (3)

Data signed: (b) (4) 08 Apr 2021 16:26:13

Generated On: 10 Jun 2021 09:56:12

SAEID	USA-US111-2020-MRNA-1273-P301000020
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LAUREN
Investigator's Last Name	CLEMENT
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/FEB/2021 13:38
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form (4)

Data signed: (b) (4) 08 Apr 2021 16:26:13

Generated On: 10 Jun 2021 09:56:12

SAEID	USA-US111-2020-MRNA-1273-P301000020
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LAUREN
Investigator's Last Name	CLEMENT
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)	07/APR/2021 11:21
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

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form (5)

Data signed: (b) (4) 08 Apr 2021 16:26:13

Generated On: 10 Jun 2021 09:56:12

SAEID	USA-US111-2020-MRNA-1273-P301000020
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LAUREN
Investigator's Last Name	CLEMENT
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)	08/APR/2021 07:39
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3812098 (Prod: Sundance Clinical Research - Platinum - PPDS)

**US3812098**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:56:12**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'US3812098'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 13:59:15

**US3812098**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:56:12**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Heather Cherniawski	10 Aug 2020 15:03:45

US3812098

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '10 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 13:59:16



**US3812098**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Clinic (Clinic)'	Heather Cherniawski (b) (4)	10 Aug 2020 15:03:45

**US3812098**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:56:12**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered 'SCRN'	System	10 Aug 2020 15:03:45

**US3812098**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered (b) (6) 1953'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 13:59:17

**US3812098**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:56:12**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '67'	Heather Cherniawski (b) (4)	10 Aug 2020 15:04:21

**US3812098**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:56:12**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered 'YEARS'	System	10 Aug 2020 15:04:21

**US3812098**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:56:12**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered '67'	System	10 Aug 2020 15:04:30

**US3812098**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:56:12**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Male (M)'	Heather Cherniawski (b) (4)	10 Aug 2020 15:04:21

**US3812098**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:56:12**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Heather Cherniawski (b) (4)	10 Aug 2020 15:04:21



**US3812098**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:56:12**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'I'	Heather Cherniawski	10 Aug 2020 15:04:21

**US3812098**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:56:12**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Heather Cherniawski (b) (4)	10 Aug 2020 15:04:21

**US3812098**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:56:12**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Heather Cherniawski (b) (4)	10 Aug 2020 15:04:21

**US3812098**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:56:12**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Heather Cherniawski (b) (4)	10 Aug 2020 15:04:21

**US3812098**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:56:12**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Heather Cherniawski (b) (4)	10 Aug 2020 15:04:21

**US3812098**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:56:12**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Heather Cherniawski (b) (4)	10 Aug 2020 15:04:21

**US3812098**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:56:12**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered empty.	Heather Cherniawski (b) (4)	10 Aug 2020 15:04:21

**US3812098**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:56:12**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Heather Cherniawski (b) (4)	10 Aug 2020 15:04:21



**US3812098**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:56:12**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Heather Cherniawski (b) (4)	10 Aug 2020 15:04:21

**US3812098**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '10 Aug 2020'	Heather Cherniawski	10 Aug 2020 15:04:30

**US3812098**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered 'Aug 2020'	System	10 Aug 2020 15:04:30

**US3812098**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered '2020'	System	10 Aug 2020 15:04:30

US3812098

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:56:12

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
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	10 Aug 2020 15:04:40
User entered 'Amendment 1 (1)' reason for change: Data Entry Error	Heather Cherniawski	10 Aug 2020 15:04:40
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	10 Aug 2020 15:04:30
	Heather Cherniawski	10 Aug 2020 15:04:30
	(b) (4)	

US3812098

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Heather Cherniawski	10 Aug 2020 15:04:30

US3812098

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:56:12

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered empty.	Heather Cherniawski	10 Aug 2020 15:04:30

**US3812098**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:56:12**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered empty.	Heather Cherniawski	10 Aug 2020 15:04:30



**US3812098**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:56:12**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'No (N)'	Heather Cherniawski	10 Aug 2020 15:04:30

**US3812098**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:56:12**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 13:59:16

**US3812098**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:56:12**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered 'I'	System	10 Aug 2020 15:05:21

**US3812098**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Heather Cherniawski	10 Aug 2020 15:05:21

**US3812098**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 10 Jun 2021 09:56:12**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	11 Aug 2020 18:46:59

US3812098

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:56:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Male genital tract therapeutic procedures NEC, PT: Vasectomy, LLT: Vasectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:28:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:28:57
Data point term sent to Coder	System	20 Feb 2021 19:41:55
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:41:45
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Male genital tract therapeutic procedures NEC, PT: Vasectomy, LLT: Vasectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 18:48:17
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 18:48:17
Data point term sent to Coder	System	11 Aug 2020 18:48:01
User entered 'VASECTOMY'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:47:18

**US3812098**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'UN UNK 2008'	Breanna Galibert (b) (4)	11 Aug 2020 18:47:18

**US3812098**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:56:12**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Breanna Galibert (b) (4)	11 Aug 2020 18:47:18



US3812098

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:56:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User closed query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Nov 2020 15:39:02
Query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. Update eCRF as appropriate. ' answered with 'corrected to include stop date' (Site from DM).	Anya Penly (b) (4) (b) (4)	21 Oct 2020 14:43:07
User entered 'No (N)' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	21 Oct 2020 14:42:52
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 18:21:44
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:47:18

**US3812098**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'un UNK 2008' reason for change:	(b) (4)	
Data Entry Error	Anya Penly (b) (4)	21 Oct 2020 14:42:52
User entered empty.	(b) (4)	
	Breanna Galibert (b) (4)	11 Aug 2020 18:47:18
	(b) (4)	

**US3812098**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:56:12**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Breanna Galibert (b) (4)	11 Aug 2020 18:47:18

**US3812098**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered 'Jan 2008'	System	11 Aug 2020 18:47:18

**US3812098**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered '2008'	System	11 Aug 2020 18:47:18

**US3812098**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered 'Jan 2008'	System	21 Oct 2020 14:42:52
User entered empty.	System	11 Aug 2020 18:47:18

**US3812098**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered '2008'	System	21 Oct 2020 14:42:52
User entered empty.	System	11 Aug 2020 18:47:18

US3812098

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:56:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Inguinal hernias, PT: Inguinal hernia, LLT: Right inguinal hernia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:28:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:28:55
Data point term sent to Coder	System	20 Feb 2021 19:41:55
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:41:45
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Inguinal hernias, PT: Inguinal hernia, LLT: Right inguinal hernia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:58:14
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 19:58:14
Data point term sent to Coder	System	11 Aug 2020 18:48:04
User entered '(R) INGUINAL HERNIA'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:48:02



**US3812098**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'UN UNK 2009'	Breanna Galibert (b) (4)	11 Aug 2020 18:48:02

**US3812098**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:56:12**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Breanna Galibert (b) (4)	11 Aug 2020 18:48:02

**US3812098**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:56:12**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'No (N)'	Breanna Galibert (b) (4)	11 Aug 2020 18:48:02

**US3812098**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'UN UNK 2009'	Breanna Galibert (b) (4)	11 Aug 2020 18:48:02

**US3812098**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:56:12**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Breanna Galibert (b) (4)	11 Aug 2020 18:48:02

**US3812098**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered 'Jan 2009'	System	11 Aug 2020 18:48:02

**US3812098**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered '2009'	System	11 Aug 2020 18:48:02

**US3812098**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered 'Jan 2009'	System	11 Aug 2020 18:48:02



**US3812098**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered '2009'	System	11 Aug 2020 18:48:02

US3812098

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:56:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Inguinal hernia repair, LLT: Inguinal hernia repair - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:16
Data point term sent to Coder	System	20 Feb 2021 19:41:55
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:41:45
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Inguinal hernia repair, LLT: Inguinal hernia repair - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:58:14
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 19:58:14
Data point term sent to Coder	System	11 Aug 2020 18:49:07
User entered '(R) INGUINAL HERNIA REPAIR'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:48:32

**US3812098**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'UN UNK 2009'	Breanna Galibert (b) (4)	11 Aug 2020 18:48:32

**US3812098**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:56:12**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Breanna Galibert (b) (4)	11 Aug 2020 18:48:32

**US3812098**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:56:12**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'No (N)'	Breanna Galibert (b) (4)	11 Aug 2020 18:48:32

**US3812098**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'UN UNK 2009'	Breanna Galibert (b) (4)	11 Aug 2020 18:48:32

**US3812098**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:56:12**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Breanna Galibert (b) (4)	11 Aug 2020 18:48:32

**US3812098**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered 'Jan 2009'	System	11 Aug 2020 18:48:32



**US3812098**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered '2009'	System	11 Aug 2020 18:48:32

**US3812098**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered 'Jan 2009'	System	11 Aug 2020 18:48:32

**US3812098**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered '2009'	System	11 Aug 2020 18:48:32

US3812098

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:56:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Skull fractures, facial bone fractures and dislocations, PT: Craniofacial fracture, LLT: Craniofacial dysjunction fracture - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	20 Feb 2021 20:13:14
Data point term sent to Coder	System	20 Feb 2021 19:41:58
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:41:45
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Skull fractures, facial bone fractures and dislocations, PT: Craniofacial fracture, LLT: Craniofacial dysjunction fracture - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 20:36:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 20:36:05
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Skull fractures, facial bone fractures and dislocations, PT: Skull fracture, LLT: Skull fracture - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 06:09:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 06:09:45
Data point term sent to Coder	System	05 Nov 2020 15:24:59
Coding entries removed.	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 15:24:13
User entered 'CRANIOFACIAL SEPARATION' reason for change: New Information	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 15:24:13
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Musculoskeletal and connective tissue disorders congenital, HLT: Musculoskeletal and connective tissue disorders of skull congenital, PT: Craniofacial deformity, LLT: Craniofacial deformity - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 08:13:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 08:13:15
Data point term sent to Coder	System	11 Aug 2020 18:49:10

US3812098

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:56:12

[Condition](#)

Audit	User	Time (GMT)
User entered 'FACIAL CRANIAL SEPERATION'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:48:58

**US3812098**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'UN UNK 1985'	Breanna Galibert (b) (4)	11 Aug 2020 18:48:58

**US3812098**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:56:12**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Breanna Galibert (b) (4)	11 Aug 2020 18:48:58

**US3812098**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:56:12**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'No (N)'	Breanna Galibert (b) (4)	11 Aug 2020 18:48:58



**US3812098**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'UN UNK 1985'	Breanna Galibert (b) (4)	11 Aug 2020 18:48:58

**US3812098**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:56:12**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Breanna Galibert (b) (4)	11 Aug 2020 18:48:58

**US3812098**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered 'Jan 1985'	System	11 Aug 2020 18:48:58

**US3812098**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered '1985'	System	11 Aug 2020 18:48:58

**US3812098**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered 'Jan 1985'	System	11 Aug 2020 18:48:58

**US3812098**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered '1985'	System	11 Aug 2020 18:48:58

US3812098

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:56:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Skull and brain therapeutic procedures, PT: Cranioplasty, LLT: Cranioplasty - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:28:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:28:58
Data point term sent to Coder	System	20 Feb 2021 19:41:56
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:41:45
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Skull and brain therapeutic procedures, PT: Cranioplasty, LLT: Cranioplasty - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 05:57:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 05:57:45
Data point term sent to Coder	System	05 Nov 2020 15:24:59
Coding entries removed.	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 15:24:34
User entered 'CRANIOFACIAL RECONSTRUCTION' reason for change: New Information	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 15:24:34
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Facial therapeutic procedures, PT: Facial operation, LLT: Facial operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 08:10:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 08:10:24
Data point term sent to Coder	System	11 Aug 2020 18:50:11
User entered 'FACIAL CRANIAL REPAIR'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:49:18

**US3812098**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'UN UNK 1985'	Breanna Galibert (b) (4)	11 Aug 2020 18:49:18



**US3812098**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:56:12**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Breanna Galibert (b) (4)	11 Aug 2020 18:49:18

**US3812098**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:56:12**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'No (N)'	Breanna Galibert (b) (4)	11 Aug 2020 18:49:18

**US3812098**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'UN UNK 1985'	Breanna Galibert (b) (4)	11 Aug 2020 18:49:18

**US3812098**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:56:12**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Breanna Galibert (b) (4)	11 Aug 2020 18:49:18

**US3812098**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered 'Jan 1985'	System	11 Aug 2020 18:49:18

**US3812098**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered '1985'	System	11 Aug 2020 18:49:18

**US3812098**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered 'Jan 1985'	System	11 Aug 2020 18:49:18

**US3812098**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered '1985'	System	11 Aug 2020 18:49:18



US3812098

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:56:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User coded data point as SOC: Nervous system disorders, HLGT: Cranial nerve disorders (excl neoplasms), HLT: Olfactory nerve disorders, PT: Anosmia, LLT: Anosmia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:04
Data point term sent to Coder	System	20 Feb 2021 19:41:58
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:41:45
User coded data point as SOC: Nervous system disorders, HLGT: Cranial nerve disorders (excl neoplasms), HLT: Olfactory nerve disorders, PT: Anosmia, LLT: Anosmia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 18:52:17
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 18:52:17
Data point term sent to Coder	System	11 Aug 2020 18:51:14
User entered 'ANOSMIA'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:50:25

**US3812098**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'UN UNK 1985'	Breanna Galibert (b) (4)	11 Aug 2020 18:50:25

**US3812098**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:56:12**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Breanna Galibert (b) (4)	11 Aug 2020 18:50:25

**US3812098**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:56:12**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	11 Aug 2020 18:50:25

**US3812098**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered empty.	Breanna Galibert (b) (4)	11 Aug 2020 18:50:25

**US3812098**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:56:12**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Breanna Galibert (b) (4)	11 Aug 2020 18:50:25

**US3812098**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered 'Jan 1985'	System	11 Aug 2020 18:50:25

**US3812098**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered '1985'	System	11 Aug 2020 18:50:25



**US3812098**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered empty.	System	11 Aug 2020 18:50:25

**US3812098**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered empty.	System	11 Aug 2020 18:50:25

US3812098

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:56:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Disability issues, PT: Eye prosthesis user, LLT: Eye prosthesis user - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:28:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:28:58
Data point term sent to Coder	System	20 Feb 2021 19:41:56
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:41:45
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Disability issues, PT: Eye prosthesis user, LLT: Eye prosthesis user - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 09:53:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 09:53:28
Data point term sent to Coder	System	21 Oct 2020 14:49:34
Coding entries removed.	Anya Penly (b) (4) (b) (4)	21 Oct 2020 14:48:42
User entered 'Dependency of right eye prosthetic' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	21 Oct 2020 14:48:42
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Disability issues, PT: Eye prosthesis user, LLT: Eye prosthesis user - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:59:16
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 19:59:16
Data point term sent to Coder	System	11 Aug 2020 18:51:15
User entered '(R) PROSTHETIC EYE'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:50:51

**US3812098**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'UN UNK 1985'	Breanna Galibert (b) (4)	11 Aug 2020 18:50:51

**US3812098**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:56:12**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Breanna Galibert (b) (4)	11 Aug 2020 18:50:51

US3812098

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:56:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User closed query 'Per DM CLR: Please review the status of this procedure as the effects of the procedure may be Ongoing but the procedure itself is not.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Nov 2020 15:39:55
Query 'Per DM CLR: Please review the status of this procedure as the effects of the procedure may be Ongoing but the procedure itself is not.' answered with 'clarified term to reflect ongoing condition, per Investigator' (Site from DM).	Anya Penly (b) (4) (b) (4)	21 Oct 2020 14:49:04
User opened query 'Per DM CLR: Please review the status of this procedure as the effects of the procedure may be Ongoing but the procedure itself is not.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 18:22:26
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:50:51

**US3812098**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered empty.	Breanna Galibert (b) (4)	11 Aug 2020 18:50:51

**US3812098**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:56:12**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Breanna Galibert (b) (4)	11 Aug 2020 18:50:51



**US3812098**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered 'Jan 1985'	System	11 Aug 2020 18:50:51

**US3812098**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered '1985'	System	11 Aug 2020 18:50:51

**US3812098**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered empty.	System	11 Aug 2020 18:50:51

**US3812098**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered empty.	System	11 Aug 2020 18:50:51

US3812098

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:56:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Road traffic accident, LLT: Motor vehicle accident - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:06
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:06
Data point term sent to Coder	System	20 Feb 2021 19:41:56
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:41:45
User closed query 'Per MM, please expand the abbreviation.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:13:00
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Road traffic accident, LLT: Motor vehicle accident - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 20:50:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 20:50:52
Data point term sent to Coder	System	22 Sep 2020 17:44:55
Query 'Per MM, please expand the abbreviation.' answered with 'expanded per query' (Site from DM).	Anya Penly (b) (4) (b) (4)	22 Sep 2020 17:44:50
Coding entries removed.	Anya Penly (b) (4) (b) (4)	22 Sep 2020 17:44:42
User entered 'HISTORY OF motor vehicle accident' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	22 Sep 2020 17:44:42
User opened query 'Per MM, please expand the abbreviation.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 09:27:06
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Road traffic accident, LLT: Motor vehicle accident - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 12:54:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 12:54:31
Data point term sent to Coder	System	11 Aug 2020 18:52:17
User entered 'HISTORY OF MVA'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:51:23

**US3812098**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '03 Nov 1985'	Breanna Galibert (b) (4)	11 Aug 2020 18:51:23

**US3812098**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:56:12**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Breanna Galibert (b) (4)	11 Aug 2020 18:51:23

**US3812098**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:56:12**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'No (N)'	Breanna Galibert (b) (4)	11 Aug 2020 18:51:23



**US3812098**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '03 Nov 1985'	Breanna Galibert (b) (4)	11 Aug 2020 18:51:23

**US3812098**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:56:12**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Breanna Galibert (b) (4)	11 Aug 2020 18:51:23

**US3812098**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered 'Nov 1985'	System	11 Aug 2020 18:51:23

**US3812098**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered '1985'	System	11 Aug 2020 18:51:23

**US3812098**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered 'Nov 1985'	System	11 Aug 2020 18:51:23

**US3812098**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered '1985'	System	11 Aug 2020 18:51:23

US3812098

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:56:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataract (left) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:07
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:07
Data point term sent to Coder	System	20 Feb 2021 19:41:58
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:41:45
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataract (left) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:56:15
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 19:56:15
Data point term sent to Coder	System	11 Aug 2020 18:52:19
User entered '(L) CATARACT'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:51:46

**US3812098**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'UN Feb 2020'	Breanna Galibert (b) (4)	11 Aug 2020 18:51:46



**US3812098**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:56:12**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Breanna Galibert (b) (4)	11 Aug 2020 18:51:46

**US3812098**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:56:12**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	11 Aug 2020 18:51:46

**US3812098**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered empty.	Breanna Galibert (b) (4)	11 Aug 2020 18:51:46

**US3812098**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:56:12**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Breanna Galibert (b) (4)	11 Aug 2020 18:51:46

**US3812098**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered 'Feb 2020'	System	11 Aug 2020 18:51:46

**US3812098**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered '2020'	System	11 Aug 2020 18:51:46

**US3812098**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered empty.	System	11 Aug 2020 18:51:46

**US3812098**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered empty.	System	11 Aug 2020 18:51:46



US3812098

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:56:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Shellfish allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:16
Data point term sent to Coder	System	20 Feb 2021 19:41:58
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:41:45
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Shellfish allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 21:35:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 21:35:19
Data point term sent to Coder	System	11 Aug 2020 18:52:19
User entered 'SHRIMP ALLERGY'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:52:11

**US3812098**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'UN UNK 2015'	Breanna Galibert (b) (4)	11 Aug 2020 18:52:11

**US3812098**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:56:12**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Breanna Galibert (b) (4)	11 Aug 2020 18:52:11

**US3812098**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:56:12**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	11 Aug 2020 18:52:11

**US3812098**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered empty.	Breanna Galibert (b) (4)	11 Aug 2020 18:52:11

**US3812098**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:56:12**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Breanna Galibert (b) (4)	11 Aug 2020 18:52:11

**US3812098**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered 'Jan 2015'	System	11 Aug 2020 18:52:11

**US3812098**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered '2015'	System	11 Aug 2020 18:52:11



**US3812098**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered empty.	System	11 Aug 2020 18:52:11

**US3812098**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered empty.	System	11 Aug 2020 18:52:11

US3812098

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:56:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Sulfonamide allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:08
Data point term sent to Coder	System	20 Feb 2021 19:41:59
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:41:45
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Sulfonamide allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 18:54:16
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 18:54:16
Data point term sent to Coder	System	11 Aug 2020 18:53:20
User entered 'SULFA ALLERGY'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:52:30

**US3812098**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'UN UNK 2015'	Breanna Galibert (b) (4)	11 Aug 2020 18:52:30

**US3812098**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:56:12**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Breanna Galibert (b) (4)	11 Aug 2020 18:52:30

**US3812098**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:56:12**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	11 Aug 2020 18:52:30

**US3812098**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered empty.	Breanna Galibert (b) (4)	11 Aug 2020 18:52:30

**US3812098**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:56:12**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Breanna Galibert (b) (4)	11 Aug 2020 18:52:30



**US3812098**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered 'Jan 2015'	System	11 Aug 2020 18:52:30

**US3812098**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered '2015'	System	11 Aug 2020 18:52:30

**US3812098**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered empty.	System	11 Aug 2020 18:52:30

**US3812098**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered empty.	System	11 Aug 2020 18:52:30

US3812098

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:56:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Alcohol product use, PT: Alcohol use, LLT: Alcohol use - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:28:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:28:57
Data point term sent to Coder	System	20 Feb 2021 19:41:58
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:41:45
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Alcohol product use, PT: Alcohol use, LLT: Alcohol use - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 20:06:14
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 20:06:14
Data point term sent to Coder	System	11 Aug 2020 18:53:23
User entered 'ALCOHOL USE-16 OZ OF WINE/DAY'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:53:08

**US3812098**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'UN UNK 2000'	Breanna Galibert (b) (4)	11 Aug 2020 18:53:08

**US3812098**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:56:12**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Breanna Galibert (b) (4)	11 Aug 2020 18:53:08

**US3812098**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:56:12**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	11 Aug 2020 18:53:08



**US3812098**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered empty.	Breanna Galibert (b) (4)	11 Aug 2020 18:53:08

**US3812098**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:56:12**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Breanna Galibert (b) (4)	11 Aug 2020 18:53:08

**US3812098**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered 'Jan 2000'	System	11 Aug 2020 18:53:08

**US3812098**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered '2000'	System	11 Aug 2020 18:53:08

**US3812098**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered empty.	System	11 Aug 2020 18:53:08

**US3812098**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered empty.	System	11 Aug 2020 18:53:08

US3812098

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:56:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:00
Data point term sent to Coder	System	20 Feb 2021 19:41:58
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:41:45
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Dec 2020 21:22:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Dec 2020 21:22:26
Data point term sent to Coder	System	04 Dec 2020 21:21:02
User entered 'Anxiety'	Angie Kean (b) (4) (b) (4)	04 Dec 2020 21:20:06

**US3812098**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'un UNK 2000'	Angie Kean (b) (4)	04 Dec 2020 21:20:06



**US3812098**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:56:12**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Angie Kean (b) (4)	04 Dec 2020 21:20:06

**US3812098**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:56:12**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Angie Kean (b) (4)	04 Dec 2020 21:20:06

**US3812098**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered empty.	Angie Kean (b) (4)	04 Dec 2020 21:20:06

**US3812098**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:56:12**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Angie Kean (b) (4)	04 Dec 2020 21:20:06

**US3812098**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered 'Jan 2000'	System	04 Dec 2020 21:20:06

**US3812098**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered '2000'	System	04 Dec 2020 21:20:06

**US3812098**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered empty.	System	04 Dec 2020 21:20:06

**US3812098**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered empty.	System	04 Dec 2020 21:20:06



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Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:56:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Water soluble vitamin deficiencies, PT: Vitamin B12 deficiency, LLT: Vitamin B12 deficiency - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:02
Data point term sent to Coder	System	20 Feb 2021 19:42:00
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:41:45
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Water soluble vitamin deficiencies, PT: Vitamin B12 deficiency, LLT: Vitamin B12 deficiency - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 22:36:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 22:36:00
Data point term sent to Coder	System	04 Dec 2020 21:21:02
User entered 'Vitamin B12-Deficiency'	Angie Kean (b) (4) (b) (4)	04 Dec 2020 21:20:32

**US3812098**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'un UNK 2019'	Angie Kean (b) (4)	04 Dec 2020 21:20:32

**US3812098**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:56:12**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Angie Kean (b) (4)	04 Dec 2020 21:20:32

**US3812098**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:56:12**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Angie Kean (b) (4)	04 Dec 2020 21:20:32

**US3812098**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered empty.	Angie Kean (b) (4)	04 Dec 2020 21:20:32

**US3812098**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:56:12**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Angie Kean (b) (4)	04 Dec 2020 21:20:32

**US3812098**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered 'Jan 2019'	System	04 Dec 2020 21:20:32

**US3812098**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered '2019'	System	04 Dec 2020 21:20:32



**US3812098**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered empty.	System	04 Dec 2020 21:20:32

**US3812098**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered empty.	System	04 Dec 2020 21:20:32

US3812098

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:56:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Urinary abnormalities, PT: Microalbuminuria, LLT: Microalbuminuria - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:05
Data point term sent to Coder	System	20 Feb 2021 19:42:02
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:41:45
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Urinary abnormalities, PT: Microalbuminuria, LLT: Microalbuminuria - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 21:34:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 21:34:53
Data point term sent to Coder	System	04 Dec 2020 21:22:03
User entered 'Microalbuminuria'	Angie Kean (b) (4) (b) (4)	04 Dec 2020 21:21:29

**US3812098**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'un Jun 2019'	Angie Kean (b) (4)	04 Dec 2020 21:21:29

**US3812098**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:56:12**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Angie Kean (b) (4)	04 Dec 2020 21:21:29

**US3812098**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:56:12**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Angie Kean (b) (4)	04 Dec 2020 21:21:29

**US3812098**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered empty.	Angie Kean (b) (4)	04 Dec 2020 21:21:29

**US3812098**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:56:12**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Angie Kean (b) (4)	04 Dec 2020 21:21:29



**US3812098**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered 'Jun 2019'	System	04 Dec 2020 21:21:29

**US3812098**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered '2019'	System	04 Dec 2020 21:21:29

**US3812098**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered empty.	System	04 Dec 2020 21:21:29

**US3812098**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered empty.	System	04 Dec 2020 21:21:29

US3812098

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:56:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid disorders NEC, PT: Thyroid mass, LLT: Thyroid nodule - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:13
Data point term sent to Coder	System	20 Feb 2021 19:42:02
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:41:45
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid disorders NEC, PT: Thyroid mass, LLT: Thyroid nodule - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Dec 2020 21:24:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Dec 2020 21:24:02
Data point term sent to Coder	System	04 Dec 2020 21:23:03
User entered 'Thyroid nodules'	Angie Kean (b) (4) (b) (4)	04 Dec 2020 21:22:04

**US3812098**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '09 Mar 2020'	Angie Kean (b) (4)	04 Dec 2020 21:22:04

**US3812098**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:56:12**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Angie Kean (b) (4)	04 Dec 2020 21:22:04

**US3812098**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:56:12**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Angie Kean (b) (4)	04 Dec 2020 21:22:04



**US3812098**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered empty.	Angie Kean (b) (4)	04 Dec 2020 21:22:04

**US3812098**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:56:12**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Angie Kean (b) (4)	04 Dec 2020 21:22:04

**US3812098**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered 'Mar 2020'	System	04 Dec 2020 21:22:04

**US3812098**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered '2020'	System	04 Dec 2020 21:22:04

**US3812098**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered empty.	System	04 Dec 2020 21:22:04

**US3812098**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered empty.	System	04 Dec 2020 21:22:04

US3812098

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:56:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:57
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Feelings and sensations NEC, PT: Sensation of foreign body, LLT: Globus feeling in pharynx - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 16:45:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 16:45:45
Data point term sent to Coder	System	17 Mar 2021 16:44:32
User entered 'Globus Sensation'	lauren clement (b) (4)	17 Mar 2021 16:43:52

**US3812098**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:57
User entered 'un UNK 2019'	lauren clement (b) (4)	17 Mar 2021 16:43:52



US3812098

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:56:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:57
User entered '0'	lauren clement (b) (4)	17 Mar 2021 16:43:52

US3812098

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:56:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:57
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	17 Mar 2021 16:43:59
User entered 'Yes (Y)' reason for change: Data Entry Error	lauren clement (b) (4)	17 Mar 2021 16:43:59
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	17 Mar 2021 16:43:52
User entered 'No (N)'	lauren clement (b) (4)	17 Mar 2021 16:43:52

**US3812098**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:57
User entered empty.	lauren clement (b) (4)	17 Mar 2021 16:43:52

US3812098

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:56:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:57
User entered '0'	lauren clement (b) (4)	17 Mar 2021 16:43:52

**US3812098**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered 'Jan 2019'	System	17 Mar 2021 16:43:52

**US3812098**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered '2019'	System	17 Mar 2021 16:43:52

**US3812098**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered empty.	System	17 Mar 2021 16:43:52

**US3812098**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered empty.	System	17 Mar 2021 16:43:52



US3812098

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	11 Aug 2020 18:54:41

**US3812098**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:56:12**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '10 Aug 2020'	Breanna Galibert (b) (4)	11 Aug 2020 18:54:41

**US3812098**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '08:07'	Breanna Galibert (b) (4)	11 Aug 2020 18:54:41

**US3812098**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered '10 Aug 2020 08:07'	System	11 Aug 2020 18:54:41

**US3812098**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '68.7' in	Breanna Galibert (b) (4)	11 Aug 2020 18:54:41
DataPoint set to visible.	System	10 Aug 2020 15:05:21

**US3812098**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '162.6' lb	Breanna Galibert (b) (4)	11 Aug 2020 18:54:41
DataPoint set to visible.	System	10 Aug 2020 15:05:21

**US3812098**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:56:12**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
Amendment Manager: User entered '24.27264'	System	16 Sep 2020 23:49:37
User entered '24.3'	System	11 Aug 2020 18:54:41
DataPoint set to visible.	System	10 Aug 2020 15:05:21

US3812098

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:12

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered 'kg/m2'	System	11 Aug 2020 18:54:41
DataPoint set to visible.	System	10 Aug 2020 15:05:21



US3812098

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	11 Aug 2020 18:54:41

US3812098

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Other (Other)'	Breanna Galibert (b) (4)	11 Aug 2020 18:54:41

**US3812098**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:56:12**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	11 Aug 2020 18:54:41

**US3812098**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:56:12**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	11 Aug 2020 18:54:41

**US3812098**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:56:12**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered 'bpm'	System	11 Aug 2020 18:54:41

US3812098

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	11 Aug 2020 18:54:41

US3812098

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered 'breaths/min'	System	11 Aug 2020 18:54:41

US3812098

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	11 Aug 2020 18:54:41



**US3812098**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:56:12**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered 'mmHg'	System	11 Aug 2020 18:54:41

US3812098

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	11 Aug 2020 18:54:41

**US3812098**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:56:12**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered 'mmHg'	System	11 Aug 2020 18:54:41

**US3812098**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:56:12**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 09:09:59

**US3812098**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:56:12**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 09:09:59

**US3812098**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:56:12**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	11 Aug 2020 18:54:53

US3812098

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:56:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Sep 2020 18:34:33
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	10 Sep 2020 14:06:11
User entered '10 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:54:53

US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'No (N)'	Breanna Galibert (b) (4)	11 Aug 2020 18:55:46



US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'No (N)'	Breanna Galibert (b) (4)	11 Aug 2020 18:55:46

US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:12

**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)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'No (N)'	Breanna Galibert (b) (4)	11 Aug 2020 18:55:46

US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:12

**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)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'No (N)'	Breanna Galibert (b) (4)	11 Aug 2020 18:55:46

US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'No (N)'	Breanna Galibert (b) (4)	11 Aug 2020 18:55:46

US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:12

[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)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'No (N)'	Breanna Galibert (b) (4)	11 Aug 2020 18:55:46

US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:12

**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)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'No (N)'	Breanna Galibert (b) (4)	11 Aug 2020 18:55:46

US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:12

**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)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'No (N)'	Breanna Galibert (b) (4)	11 Aug 2020 18:55:46

US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:12

[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)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'No (N)'	Breanna Galibert (b) (4)	11 Aug 2020 18:55:46



US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:12

**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)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	11 Aug 2020 18:55:46

US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:12

**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)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'No (N)'	Breanna Galibert (b) (4)	11 Aug 2020 18:55:46

**US3812098**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:56:12**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	11 Aug 2020 18:55:46

US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:12

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'BABYSITS'	Breanna Galibert (b) (4)	11 Aug 2020 18:55:46

US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:12

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'I'	Breanna Galibert (b) (4)	11 Aug 2020 18:55:46

US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:12

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Breanna Galibert (b) (4)	11 Aug 2020 18:55:46

US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:12

**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)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Breanna Galibert (b) (4)	11 Aug 2020 18:55:46

US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:12

[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)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Breanna Galibert (b) (4)	11 Aug 2020 18:55:46



US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:12

**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)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Breanna Galibert (b) (4)	11 Aug 2020 18:55:46

US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:12

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Breanna Galibert (b) (4)	11 Aug 2020 18:55:46

**US3812098**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:56:12**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '0'	Breanna Galibert (b) (4)	11 Aug 2020 18:55:46

US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:12

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered empty.	Breanna Galibert (b) (4)	11 Aug 2020 18:55:46

US3812098

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:56:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Heather Cherniawski	10 Aug 2020 15:05:36

**US3812098**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '10 Aug 2020'	Heather Cherniawski	10 Aug 2020 15:05:36

US3812098

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:56:12

[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 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Clinic (Clinic)'	Heather Cherniawski (b) (4)	10 Aug 2020 15:05:36

**US3812098**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:56:12**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'VISIT1'	System	10 Aug 2020 15:05:36



US3812098

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '10 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 14:19:30

US3812098

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:56:12

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 03:14:07
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:14:07
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Aug 2020 14:19:30
User entered '185352' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 14:19:30

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:56:12

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 14:19:30

US3812098

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:56:12

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 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'No (N)'	Breanna Galibert (b) (4)	11 Aug 2020 18:56:06

US3812098

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:56:12

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 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'No (N)'	Breanna Galibert (b) (4)	11 Aug 2020 18:56:06

US3812098

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'No (N)'	Breanna Galibert (b) (4)	11 Aug 2020 18:56:06

**US3812098**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:56:12**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'No (N)'	Breanna Galibert (b) (4)	11 Aug 2020 18:56:06

US3812098

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:56:12

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'No (N)'	Breanna Galibert (b) (4)	11 Aug 2020 18:56:06



US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:56:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:56:12

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:56:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:56:12

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User accepted default value 'Pre-Dose (PREDOSE)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '10 Aug 2020'	Breanna Galibert (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '08:07'	Breanna Galibert (b) (4)	11 Aug 2020 18:58:28



US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered '10 Aug 2020 08:07'	System	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '97.9' F	Breanna Galibert (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered empty.	Breanna Galibert (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '73'	Breanna Galibert (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'bpm'	System	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '13'	Breanna Galibert (b) (4)	11 Aug 2020 18:58:28

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'breaths/min'	System	11 Aug 2020 18:58:28



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '128'	Breanna Galibert (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'mmHg'	System	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '78'	Breanna Galibert (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'mmHg'	System	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:56:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:56:12

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User accepted default value 'Post-Dose (POSTDOSE)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	11 Aug 2020 18:58:28



US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '10 Aug 2020'	Breanna Galibert (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	18 Aug 2020 13:27:43
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 18:58:28
User entered '10:19'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered '10 Aug 2020 10:19'	System	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '97.9' F	Breanna Galibert (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered empty.	Breanna Galibert (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '68'	Breanna Galibert (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'bpm'	System	11 Aug 2020 18:58:28



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '15'	Breanna Galibert (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'breaths/min'	System	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '130'	Breanna Galibert (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'mmHg'	System	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '74'	Breanna Galibert (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'mmHg'	System	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:56:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'No (N)'	Breanna Galibert (b) (4)	11 Aug 2020 18:56:47

US3812098

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:56:12

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered empty.	Breanna Galibert (b) (4)	11 Aug 2020 18:56:47



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:56:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Heather Cherniawski	10 Aug 2020 15:07:32

US3812098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:56:12

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered empty.	Heather Cherniawski (b) (4)	10 Aug 2020 15:07:32

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:56:12

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 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered empty.	Heather Cherniawski (b) (4)	10 Aug 2020 15:07:32

US3812098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:56:12

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'MRNA-1273 OR PLACEBO'	System	10 Aug 2020 15:07:32

US3812098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:56:12

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '10 Aug 2020'	Heather Cherniawski	10 Aug 2020 15:07:32

US3812098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:56:12

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '09:47'	Heather Cherniawski	10 Aug 2020 15:07:32

US3812098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:56:12

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered '10 Aug 2020 09:47'	System	10 Aug 2020 15:07:32

US3812098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:56:12

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Left Arm (LEFT ARM)'	Heather Cherniawski	10 Aug 2020 15:07:32



US3812098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:56:12

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'ONCE'	System	10 Aug 2020 15:07:32

US3812098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:56:12

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'INTRAMUSCULAR'	System	10 Aug 2020 15:07:32

US3812098

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	11 Aug 2020 18:56:22

US3812098

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '10 Aug 2020'	Breanna Galibert (b) (4)	11 Aug 2020 18:56:22

**US3812098**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:56:12**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '09:20'	Breanna Galibert (b) (4)	11 Aug 2020 18:56:22

**US3812098**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:56:12**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered '10 Aug 2020 09:20'	System	11 Aug 2020 18:56:22

US3812098

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:56:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '10 Aug 2020'	Breanna Galibert (b) (4)	11 Aug 2020 18:56:44

**US3812098**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:56:12**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:56:44



US3812098

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:56:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	11 Aug 2020 18:56:44

**US3812098**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:56:12**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '09:25'	Breanna Galibert (b) (4)	11 Aug 2020 18:56:44

**US3812098**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:56:12**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered '10 Aug 2020 09:25'	System	11 Aug 2020 18:56:44

US3812098

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:56:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:56:44

US3812098

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:56:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'No (N)'	Breanna Galibert (b) (4)	11 Aug 2020 18:56:44

**US3812098**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered empty.	Breanna Galibert (b) (4)	11 Aug 2020 18:56:44

**US3812098**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:56:12**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered empty.	System	11 Aug 2020 18:56:44

US3812098

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:56:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Angie Kean (b) (4)	18 Aug 2020 18:27:26



**US3812098**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:56:12**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'I'	System	18 Aug 2020 18:27:26

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T10:23:51', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '02038dfe-8704-4635-930b-ec3d64220815' User entered 'Yes (Y)'	System	10 Aug 2020 15:24:59
	System	10 Aug 2020 15:24:59

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T10:24:27', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '02038dfe-8704-4635-930b-ec3d64220815' User entered '97.9'	System	10 Aug 2020 15:24:59
	System	10 Aug 2020 15:24:59

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T10:24:08', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '02038dfe-8704-4635-930b-ec3d64220815' User entered 'No (N)'	System	10 Aug 2020 15:24:59
	System	10 Aug 2020 15:24:59

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T10:24:58', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '02038dfe-8704-4635-930b-ec3d64220815' User entered '10 Aug 2020 10:24'	System	10 Aug 2020 15:24:59
	System	10 Aug 2020 15:24:59

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '10 Aug 2020 10:07'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '10 Aug 2020 12:37'	System	10 Aug 2020 15:07:32



US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T17:58:33', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '83ac1035-f2a9-4c8d-a9cd-59c217c324f1' User entered 'Yes (Y)'	System	10 Aug 2020 22:59:02
	System	10 Aug 2020 22:59:02

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T17:58:41', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '83ac1035-f2a9-4c8d-a9cd-59c217c324f1' User entered '99.5'	System	10 Aug 2020 22:59:02
	System	10 Aug 2020 22:59:02

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T17:58:47', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '83ac1035-f2a9-4c8d-a9cd-59c217c324f1'	System	10 Aug 2020 22:59:02
User entered 'No (N)'	System	10 Aug 2020 22:59:02

**US3812098**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T17:58:58', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '83ac1035-f2a9-4c8d-a9cd-59c217c324f1' User entered '10 Aug 2020 17:58'	System	10 Aug 2020 22:59:02
	System	10 Aug 2020 22:59:02

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '10 Aug 2020 13:32'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 2'	System	10 Aug 2020 15:07:32



US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:56:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-11T16:58:32', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '5df582da-cea8-48f3-81b8-06eaa301e75e' User entered 'Yes (Y)'	System	11 Aug 2020 21:59:01
	System	11 Aug 2020 21:59:01

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:56:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-11T16:58:40', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '5df582da-cea8-48f3-81b8-06eaa301e75e' User entered '98.4'	System	11 Aug 2020 21:59:01
	System	11 Aug 2020 21:59:01

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-11T16:58:47', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '5df582da-cea8-48f3-81b8-06eaa301e75e' User entered 'No (N)'	System	11 Aug 2020 21:59:01
	System	11 Aug 2020 21:59:01

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:56:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-11T16:58:59', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '5df582da-cea8-48f3-81b8-06eaa301e75e'	System	11 Aug 2020 21:59:01
User entered '11 Aug 2020 16:58'	System	11 Aug 2020 21:59:01

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 3'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:56:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-12T16:39:34', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ad046827-ae67-4557-b502-b38a904f73cd' User entered 'Yes (Y)'	System	12 Aug 2020 21:40:06
	System	12 Aug 2020 21:40:06



US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:56:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-12T16:39:43', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ad046827-ae67-4557-b502-b38a904f73cd' User entered '99.4'	System	12 Aug 2020 21:40:06
	System	12 Aug 2020 21:40:06

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-12T16:39:48', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ad046827-ae67-4557-b502-b38a904f73cd' User entered 'No (N)'	System	12 Aug 2020 21:40:06
	System	12 Aug 2020 21:40:06

**US3812098**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-12T16:39:55', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ad046827-ae67-4557-b502-b38a904f73cd' User entered '12 Aug 2020 16:39'	System	12 Aug 2020 21:40:06
	System	12 Aug 2020 21:40:06

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 4'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:56:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-13T15:13:43', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ec81e64b-79a2-4744-ad07-a5c73cc00802' User entered 'Yes (Y)'	System	13 Aug 2020 20:14:21
	System	13 Aug 2020 20:14:21

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:56:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-13T15:13:50', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ec81e64b-79a2-4744-ad07-a5c73cc00802' User entered '98.5'	System	13 Aug 2020 20:14:21
	System	13 Aug 2020 20:14:21



US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-13T15:13:55', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ec81e64b-79a2-4744-ad07-a5c73cc00802'	System	13 Aug 2020 20:14:21
User entered 'No (N)'	System	13 Aug 2020 20:14:21

**US3812098**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-13T15:14:01', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ec81e64b-79a2-4744-ad07-a5c73cc00802'	System	13 Aug 2020 20:14:21
User entered '13 Aug 2020 15:14'	System	13 Aug 2020 20:14:21

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 5'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:56:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-14T15:51:28', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '2f34a237-7b52-4048-8988-814363a68b68'	System	14 Aug 2020 20:52:26
User entered 'Yes (Y)'	System	14 Aug 2020 20:52:26

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:56:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-14T15:51:34', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '2f34a237-7b52-4048-8988-814363a68b68' User entered '98.6'	System	14 Aug 2020 20:52:26
	System	14 Aug 2020 20:52:26

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-14T15:52:18', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '2f34a237-7b52-4048-8988-814363a68b68'	System	14 Aug 2020 20:52:26
User entered 'No (N)'	System	14 Aug 2020 20:52:26



**US3812098**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-14T15:52:24', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '2f34a237-7b52-4048-8988-814363a68b68'	System	14 Aug 2020 20:52:26
User entered '14 Aug 2020 15:52'	System	14 Aug 2020 20:52:26

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 6'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:56:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-15T18:40:54', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e45edfee-a0e3-43b8-acaf-d80444f98e51'	System	17 Aug 2020 00:04:52
User entered 'Yes (Y)'	System	17 Aug 2020 00:04:52

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:56:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-15T18:41:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e45edfee-a0e3-43b8-acaf-d80444f98e51' User entered '98.6'	System	17 Aug 2020 00:04:52
	System	17 Aug 2020 00:04:52

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-15T18:41:04', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e45edfee-a0e3-43b8-acaf-d80444f98e51'	System	17 Aug 2020 00:04:52
User entered 'No (N)'	System	17 Aug 2020 00:04:52

**US3812098**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-15T18:41:10', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e45edfee-a0e3-43b8-acaf-d80444f98e51'	System	17 Aug 2020 00:04:52
User entered '15 Aug 2020 18:41'	System	17 Aug 2020 00:04:52



US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 7'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:56:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-16T19:06:40', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '17a182cd-3afb-4fb9-a586-63eb7e93ee93' User entered 'Yes (Y)'	System	17 Aug 2020 00:07:39
	System	17 Aug 2020 00:07:39

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:56:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-16T19:06:50', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '17a182cd-3afb-4fb9-a586-63eb7e93ee93' User entered '98.0'	System	17 Aug 2020 00:07:39
	System	17 Aug 2020 00:07:39

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-16T19:07:32', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '17a182cd-3afb-4fb9-a586-63eb7e93ee93'	System	17 Aug 2020 00:07:39
User entered 'No (N)'	System	17 Aug 2020 00:07:39

**US3812098**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-16T19:07:37', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '17a182cd-3afb-4fb9-a586-63eb7e93ee93' User entered '16 Aug 2020 19:07'	System	17 Aug 2020 00:07:39
	System	17 Aug 2020 00:07:39

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 15:07:32



US3812098

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T10:25:14', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9ae0ea8e-2c95-4db6-9df2-3a11ea49d625'	System	10 Aug 2020 15:26:01
User entered 'None (1)'	System	10 Aug 2020 15:26:01

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T10:25:25', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9ae0ea8e-2c95-4db6-9df2-3a11ea49d625' User entered 'No (N)'	System	10 Aug 2020 15:26:01
	System	10 Aug 2020 15:26:01

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T10:25:37', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9ae0ea8e-2c95-4db6-9df2-3a11ea49d625' User entered 'No (N)'	System	10 Aug 2020 15:26:01
	System	10 Aug 2020 15:26:01

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T10:25:49', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9ae0ea8e-2c95-4db6-9df2-3a11ea49d625' User entered 'None (1)'	System	10 Aug 2020 15:26:01
	System	10 Aug 2020 15:26:01

**US3812098**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T10:25:59', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9ae0ea8e-2c95-4db6-9df2-3a11ea49d625' User entered '10 Aug 2020 10:25'	System	10 Aug 2020 15:26:01
	System	10 Aug 2020 15:26:01

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '10 Aug 2020 10:07'	System	10 Aug 2020 15:07:32



US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '10 Aug 2020 12:37'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T17:59:17', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '59aaaf74-e7e1-48aa-9607-ab5eb33e6071'	System	10 Aug 2020 23:00:11
User entered 'Does not interfere with activity (2)'	System	10 Aug 2020 23:00:11

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T17:59:24', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '59aaaf74-e7e1-48aa-9607-ab5eb33e6071' User entered 'No (N)'	System	10 Aug 2020 23:00:11
	System	10 Aug 2020 23:00:11

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T17:59:32', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '59aaaf74-e7e1-48aa-9607-ab5eb33e6071' User entered 'No (N)'	System	10 Aug 2020 23:00:11
	System	10 Aug 2020 23:00:11

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T17:59:53', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '59aaaf74-e7e1-48aa-9607-ab5eb33e6071' User entered 'None (1)'	System	10 Aug 2020 23:00:11
	System	10 Aug 2020 23:00:11

**US3812098**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T18:00:10', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '59aaaf74-e7e1-48aa-9607-ab5eb33e6071'	System	10 Aug 2020 23:00:11
User entered '10 Aug 2020 18:00'	System	10 Aug 2020 23:00:11

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '10 Aug 2020 13:32'	System	10 Aug 2020 15:07:32



US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 2'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:56:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-11T16:59:14', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '62f308b1-5ed3-4847-92a8-c31bf96e17b4'	System	11 Aug 2020 21:59:50
User entered 'Does not interfere with activity (2)'	System	11 Aug 2020 21:59:50

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:56:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-11T16:59:18', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '62f308b1-5ed3-4847-92a8-c31bf96e17b4' User entered 'No (N)'	System	11 Aug 2020 21:59:50
	System	11 Aug 2020 21:59:50

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-11T16:59:27', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '62f308b1-5ed3-4847-92a8-c31bf96e17b4' User entered 'No (N)'	System	11 Aug 2020 21:59:50
	System	11 Aug 2020 21:59:50

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:56:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-11T16:59:38', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '62f308b1-5ed3-4847-92a8-c31bf96e17b4' User entered 'None (1)'	System	11 Aug 2020 21:59:50
	System	11 Aug 2020 21:59:50

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:56:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-11T16:59:49', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '62f308b1-5ed3-4847-92a8-c31bf96e17b4'	System	11 Aug 2020 21:59:50
User entered '11 Aug 2020 16:59'	System	11 Aug 2020 21:59:50

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 15:07:32



US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 3'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:56:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-12T16:40:07', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '7725581f-cc0b-4462-825e-21e5b5f5878b' User entered 'None (1)'	System	12 Aug 2020 21:41:07
	System	12 Aug 2020 21:41:07

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:56:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-12T16:40:11', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '7725581f-cc0b-4462-825e-21e5b5f5878b' User entered 'No (N)'	System	12 Aug 2020 21:41:07
	System	12 Aug 2020 21:41:07

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-12T16:40:15', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '7725581f-cc0b-4462-825e-21e5b5f5878b' User entered 'No (N)'	System	12 Aug 2020 21:41:07
	System	12 Aug 2020 21:41:07

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:56:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-12T16:40:30', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '7725581f-cc0b-4462-825e-21e5b5f5878b' User entered 'None (1)'	System	12 Aug 2020 21:41:07
	System	12 Aug 2020 21:41:07

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:56:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-12T16:40:37', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '7725581f-cc0b-4462-825e-21e5b5f5878b' User entered '12 Aug 2020 16:40'	System	12 Aug 2020 21:41:07
	System	12 Aug 2020 21:41:07

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 15:07:32



US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 4'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:56:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-13T15:14:07', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ee5187fc-9964-486b-9178-317d3a3c3521' User entered 'None (1)'	System	13 Aug 2020 20:14:31
	System	13 Aug 2020 20:14:31

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:56:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-13T15:14:11', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ee5187fc-9964-486b-9178-317d3a3c3521' User entered 'No (N)'	System	13 Aug 2020 20:14:31
	System	13 Aug 2020 20:14:31

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-13T15:14:15', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ee5187fc-9964-486b-9178-317d3a3c3521' User entered 'No (N)'	System	13 Aug 2020 20:14:31
	System	13 Aug 2020 20:14:31

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:56:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-13T15:14:19', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ee5187fc-9964-486b-9178-317d3a3c3521' User entered 'None (1)'	System	13 Aug 2020 20:14:31
	System	13 Aug 2020 20:14:31

**US3812098**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-13T15:14:29', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ee5187fc-9964-486b-9178-317d3a3c3521' User entered '13 Aug 2020 15:14'	System	13 Aug 2020 20:14:31
	System	13 Aug 2020 20:14:31

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 15:07:32



US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 5'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:56:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-14T15:52:32', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e8951df1-e46f-4a39-bde6-3563ad76f560'	System	14 Aug 2020 20:53:02
User entered 'None (1)'	System	14 Aug 2020 20:53:02

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:56:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-14T15:52:36', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e8951df1-e46f-4a39-bde6-3563ad76f560'	System	14 Aug 2020 20:53:02
User entered 'No (N)'	System	14 Aug 2020 20:53:02

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-14T15:52:39', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e8951df1-e46f-4a39-bde6-3563ad76f560'	System	14 Aug 2020 20:53:02
User entered 'No (N)'	System	14 Aug 2020 20:53:02

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:56:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-14T15:52:46', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e8951df1-e46f-4a39-bde6-3563ad76f560'	System	14 Aug 2020 20:53:02
User entered 'None (1)'	System	14 Aug 2020 20:53:02

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:56:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-14T15:52:59', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e8951df1-e46f-4a39-bde6-3563ad76f560'	System	14 Aug 2020 20:53:02
User entered '14 Aug 2020 15:52'	System	14 Aug 2020 20:53:02

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 15:07:32



US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 6'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:56:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-15T18:41:16', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '8a5d35ff-44dd-4f3f-9281-f14d7b15acf6'	System	17 Aug 2020 00:04:54
User entered 'None (1)'	System	17 Aug 2020 00:04:54

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:56:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-15T18:41:22', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '8a5d35ff-44dd-4f3f-9281-f14d7b15acf6'	System	17 Aug 2020 00:04:54
User entered 'No (N)'	System	17 Aug 2020 00:04:54

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-15T18:41:28', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '8a5d35ff-44dd-4f3f-9281-f14d7b15acf6'	System	17 Aug 2020 00:04:54
User entered 'No (N)'	System	17 Aug 2020 00:04:54

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:56:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-15T18:41:31', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '8a5d35ff-44dd-4f3f-9281-f14d7b15acf6'	System	17 Aug 2020 00:04:54
User entered 'None (1)'	System	17 Aug 2020 00:04:54

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:56:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-15T18:41:37', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '8a5d35ff-44dd-4f3f-9281-f14d7b15acf6'	System	17 Aug 2020 00:04:54
User entered '15 Aug 2020 18:41'	System	17 Aug 2020 00:04:54

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 15:07:32



US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 7'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:56:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-16T19:07:44', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '2c933b79-d6d2-4f9d-bbb7-7da546186b50'	System	17 Aug 2020 00:08:04
User entered 'None (1)'	System	17 Aug 2020 00:08:04

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:56:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-16T19:07:48', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '2c933b79-d6d2-4f9d-bbb7-7da546186b50'	System	17 Aug 2020 00:08:04
User entered 'No (N)'	System	17 Aug 2020 00:08:04

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-16T19:07:52', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '2c933b79-d6d2-4f9d-bbb7-7da546186b50'	System	17 Aug 2020 00:08:04
User entered 'No (N)'	System	17 Aug 2020 00:08:04

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:56:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-16T19:07:55', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '2c933b79-d6d2-4f9d-bbb7-7da546186b50'	System	17 Aug 2020 00:08:04
User entered 'None (1)'	System	17 Aug 2020 00:08:04

**US3812098**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-16T19:08:01', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '2c933b79-d6d2-4f9d-bbb7-7da546186b50'	System	17 Aug 2020 00:08:04
User entered '16 Aug 2020 19:08'	System	17 Aug 2020 00:08:04

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 15:07:32



US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T10:26:06', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'b7615b79-815f-45ca-8afe-761764737044'	System	10 Aug 2020 15:27:02
User entered 'None (0)'	System	10 Aug 2020 15:27:02

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T10:26:10', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'b7615b79-815f-45ca-8afe-761764737044'	System	10 Aug 2020 15:27:02
User entered 'None (0)'	System	10 Aug 2020 15:27:02

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T10:26:14', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'b7615b79-815f-45ca-8afe-761764737044'	System	10 Aug 2020 15:27:02
User entered 'None (0)'	System	10 Aug 2020 15:27:02

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T10:26:18', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'b7615b79-815f-45ca-8afe-761764737044' User entered 'None (0)'	System	10 Aug 2020 15:27:02
	System	10 Aug 2020 15:27:02

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T10:26:25', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'b7615b79-815f-45ca-8afe-761764737044' User entered 'None (0)'	System	10 Aug 2020 15:27:02
	System	10 Aug 2020 15:27:02

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T10:26:27', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'b7615b79-815f-45ca-8afe-761764737044' User entered 'None (0)'	System	10 Aug 2020 15:27:02
	System	10 Aug 2020 15:27:02



US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

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)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T10:26:41', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'b7615b79-815f-45ca-8afe-761764737044'	System	10 Aug 2020 15:27:02
User entered 'No (N)'	System	10 Aug 2020 15:27:02

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T10:27:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'b7615b79-815f-45ca-8afe-761764737044'	System	10 Aug 2020 15:27:02
User entered '10 Aug 2020 10:27'	System	10 Aug 2020 15:27:02

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '10 Aug 2020 10:07'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '10 Aug 2020 12:37'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T18:00:19', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'c6acc1bc-4c10-4dcd-9d8e-a3551ae6f97b' User entered 'None (0)'	System	10 Aug 2020 23:01:16
	System	10 Aug 2020 23:01:16

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T18:00:26', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'c6acc1bc-4c10-4dcd-9d8e-a3551ae6f97b'	System	10 Aug 2020 23:01:16
User entered 'No interference with activity (1)'	System	10 Aug 2020 23:01:16

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T18:00:32', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'c6acc1bc-4c10-4dcd-9d8e-a3551ae6f97b'	System	10 Aug 2020 23:01:16
User entered 'No interference with activity (1)'	System	10 Aug 2020 23:01:16



US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T18:00:39', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'c6acc1bc-4c10-4dcd-9d8e-a3551ae6f97b' User entered 'None (0)'	System	10 Aug 2020 23:01:16
	System	10 Aug 2020 23:01:16

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T18:00:43', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'c6acc1bc-4c10-4dcd-9d8e-a3551ae6f97b' User entered 'None (0)'	System	10 Aug 2020 23:01:16
	System	10 Aug 2020 23:01:16

**US3812098**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:56:12**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T18:00:47', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'c6acc1bc-4c10-4dcd-9d8e-a3551ae6f97b' User entered 'None (0)'	System	10 Aug 2020 23:01:16
	System	10 Aug 2020 23:01:16

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

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)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T18:00:55', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'c6acc1bc-4c10-4dcd-9d8e-a3551ae6f97b' User entered 'No (N)'	System	10 Aug 2020 23:01:16
	System	10 Aug 2020 23:01:16

**US3812098**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T18:01:14', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'c6acc1bc-4c10-4dcd-9d8e-a3551ae6f97b' User entered '10 Aug 2020 18:01'	System	10 Aug 2020 23:01:16
	System	10 Aug 2020 23:01:16

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '10 Aug 2020 13:32'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 2'	System	10 Aug 2020 15:07:32



US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:12

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-11T17:00:06', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e239f591-1baa-4d0a-b961-f7323524f715' User entered 'None (0)'	System	11 Aug 2020 22:00:58
	System	11 Aug 2020 22:00:58

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:12

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-11T17:00:11', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e239f591-1baa-4d0a-b961-f7323524f715' User entered 'None (0)'	System	11 Aug 2020 22:00:58
	System	11 Aug 2020 22:00:58

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:12

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-11T17:00:17', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e239f591-1baa-4d0a-b961-f7323524f715' User entered 'None (0)'	System	11 Aug 2020 22:00:58
	System	11 Aug 2020 22:00:58

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:12

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-11T17:00:22', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e239f591-1baa-4d0a-b961-f7323524f715' User entered 'None (0)'	System	11 Aug 2020 22:00:58
	System	11 Aug 2020 22:00:58

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:12

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-11T17:00:33', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e239f591-1baa-4d0a-b961-f7323524f715' User entered 'None (0)'	System	11 Aug 2020 22:00:58
	System	11 Aug 2020 22:00:58

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:12

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-11T17:00:42', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e239f591-1baa-4d0a-b961-f7323524f715' User entered 'None (0)'	System	11 Aug 2020 22:00:58
	System	11 Aug 2020 22:00:58

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:12

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)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-11T17:00:47', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e239f591-1baa-4d0a-b961-f7323524f715'	System	11 Aug 2020 22:00:58
User entered 'No (N)'	System	11 Aug 2020 22:00:58

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-11T17:00:57', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e239f591-1baa-4d0a-b961-f7323524f715'	System	11 Aug 2020 22:00:58
User entered '11 Aug 2020 17:00'	System	11 Aug 2020 22:00:58



US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 3'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:12

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-12T16:40:52', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a6b420ae-e23b-4662-9d6e-aea39e176fb6' User entered 'None (0)'	System	12 Aug 2020 21:41:51
	System	12 Aug 2020 21:41:51

**US3812098**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:56:12**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-12T16:40:56', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a6b420ae-e23b-4662-9d6e-aea39e176fb6'	System	12 Aug 2020 21:41:51
User entered 'No interference with activity (1)'	System	12 Aug 2020 21:41:51

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:12

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-12T16:41:03', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a6b420ae-e23b-4662-9d6e-aea39e176fb6'	System	12 Aug 2020 21:41:51
User entered 'No interference with activity (1)'	System	12 Aug 2020 21:41:51

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:12

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-12T16:41:07', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a6b420ae-e23b-4662-9d6e-aea39e176fb6' User entered 'None (0)'	System	12 Aug 2020 21:41:51
	System	12 Aug 2020 21:41:51

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:12

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-12T16:41:10', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a6b420ae-e23b-4662-9d6e-aea39e176fb6' User entered 'None (0)'	System	12 Aug 2020 21:41:51
	System	12 Aug 2020 21:41:51



**US3812098**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:56:12**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-12T16:41:13', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a6b420ae-e23b-4662-9d6e-aea39e176fb6' User entered 'None (0)'	System	12 Aug 2020 21:41:51
	System	12 Aug 2020 21:41:51

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:12

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)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-12T16:41:18', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a6b420ae-e23b-4662-9d6e-aea39e176fb6' User entered 'No (N)'	System	12 Aug 2020 21:41:51
	System	12 Aug 2020 21:41:51

**US3812098**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-12T16:41:31', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a6b420ae-e23b-4662-9d6e-aea39e176fb6' User entered '12 Aug 2020 16:41'	System	12 Aug 2020 21:41:51
	System	12 Aug 2020 21:41:51

**US3812098**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 4'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:12

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-13T15:14:37', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '375f9da9-f53c-4234-bbeb-de6d229b9fed' User entered 'None (0)'	System	13 Aug 2020 20:15:14
	System	13 Aug 2020 20:15:14

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:12

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-13T15:14:40', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '375f9da9-f53c-4234-bbeb-de6d229b9fed' User entered 'None (0)'	System	13 Aug 2020 20:15:14
	System	13 Aug 2020 20:15:14



US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:12

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-13T15:14:43', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '375f9da9-f53c-4234-bbeb-de6d229b9fed' User entered 'None (0)'	System	13 Aug 2020 20:15:14
	System	13 Aug 2020 20:15:14

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:12

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-13T15:14:47', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '375f9da9-f53c-4234-bbeb-de6d229b9fed' User entered 'None (0)'	System	13 Aug 2020 20:15:14
	System	13 Aug 2020 20:15:14

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:12

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-13T15:14:53', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '375f9da9-f53c-4234-bbeb-de6d229b9fed' User entered 'None (0)'	System	13 Aug 2020 20:15:14
	System	13 Aug 2020 20:15:14

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:12

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-13T15:14:56', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '375f9da9-f53c-4234-bbeb-de6d229b9fed' User entered 'None (0)'	System	13 Aug 2020 20:15:14
	System	13 Aug 2020 20:15:14

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:12

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)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-13T15:15:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '375f9da9-f53c-4234-bbeb-de6d229b9fed' User entered 'No (N)'	System	13 Aug 2020 20:15:14
	System	13 Aug 2020 20:15:14

**US3812098**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-13T15:15:11', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '375f9da9-f53c-4234-bbeb-de6d229b9fed' User entered '13 Aug 2020 15:15'	System	13 Aug 2020 20:15:14
	System	13 Aug 2020 20:15:14

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 15:07:32



US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 5'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:12

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-14T15:53:04', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '3718da79-1192-4dcd-b5bb-41c7f5454e4f' User entered 'None (0)'	System	14 Aug 2020 20:53:51
	System	14 Aug 2020 20:53:51

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:12

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-14T15:53:07', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '3718da79-1192-4dcd-b5bb-41c7f5454e4f' User entered 'None (0)'	System	14 Aug 2020 20:53:51
	System	14 Aug 2020 20:53:51

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:12

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-14T15:53:16', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '3718da79-1192-4dcd-b5bb-41c7f5454e4f' User entered 'None (0)'	System	14 Aug 2020 20:53:51
	System	14 Aug 2020 20:53:51

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:12

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-14T15:53:20', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '3718da79-1192-4dcd-b5bb-41c7f5454e4f' User entered 'None (0)'	System	14 Aug 2020 20:53:51
	System	14 Aug 2020 20:53:51

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:12

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-14T15:53:23', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '3718da79-1192-4dcd-b5bb-41c7f5454e4f' User entered 'None (0)'	System	14 Aug 2020 20:53:51
	System	14 Aug 2020 20:53:51

**US3812098**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:56:12**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-14T15:53:26', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '3718da79-1192-4dcd-b5bb-41c7f5454e4f' User entered 'None (0)'	System	14 Aug 2020 20:53:51
	System	14 Aug 2020 20:53:51

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:12

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)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-14T15:53:32', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '3718da79-1192-4dcd-b5bb-41c7f5454e4f' User entered 'No (N)'	System	14 Aug 2020 20:53:51
	System	14 Aug 2020 20:53:51



**US3812098**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-14T15:53:47', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '3718da79-1192-4dcd-b5bb-41c7f5454e4f' User entered '14 Aug 2020 15:53'	System	14 Aug 2020 20:53:51
	System	14 Aug 2020 20:53:51

**US3812098**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 15:07:32

**US3812098**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 6'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:12

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-15T18:41:42', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '283e417d-aef0-497e-9619-aa640ab90a91' User entered 'None (0)'	System	17 Aug 2020 00:04:54
	System	17 Aug 2020 00:04:54

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:12

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-15T18:41:45', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '283e417d-aef0-497e-9619-aa640ab90a91' User entered 'None (0)'	System	17 Aug 2020 00:04:54
	System	17 Aug 2020 00:04:54

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:12

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-15T18:41:48', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '283e417d-aef0-497e-9619-aa640ab90a91' User entered 'None (0)'	System	17 Aug 2020 00:04:54
	System	17 Aug 2020 00:04:54

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:12

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-15T18:41:51', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '283e417d-aef0-497e-9619-aa640ab90a91' User entered 'None (0)'	System	17 Aug 2020 00:04:54
	System	17 Aug 2020 00:04:54



**US3812098**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:56:12**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-15T18:41:54', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '283e417d-aef0-497e-9619-aa640ab90a91' User entered 'None (0)'	System	17 Aug 2020 00:04:54
	System	17 Aug 2020 00:04:54

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:12

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-15T18:41:57', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '283e417d-aef0-497e-9619-aa640ab90a91' User entered 'None (0)'	System	17 Aug 2020 00:04:54
	System	17 Aug 2020 00:04:54

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:12

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)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-15T18:42:02', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '283e417d-aef0-497e-9619-aa640ab90a91' User entered 'No (N)'	System	17 Aug 2020 00:04:54
	System	17 Aug 2020 00:04:54

**US3812098**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-15T18:42:09', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '283e417d-aef0-497e-9619-aa640ab90a91' User entered '15 Aug 2020 18:42'	System	17 Aug 2020 00:04:54
	System	17 Aug 2020 00:04:54

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 7'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:12

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-16T19:08:08', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '51518870-e27c-452d-8ff6-418a4cfd862'	System	17 Aug 2020 00:08:47
User entered 'None (0)'	System	17 Aug 2020 00:08:47



US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:12

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-16T19:08:12', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '51518870-e27c-452d-8ff6-418a4cfd862' User entered 'None (0)'	System	17 Aug 2020 00:08:47
	System	17 Aug 2020 00:08:47

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:12

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-16T19:08:14', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '51518870-e27c-452d-8ff6-418a4cfd862'	System	17 Aug 2020 00:08:47
User entered 'None (0)'	System	17 Aug 2020 00:08:47

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:12

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-16T19:08:18', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '51518870-e27c-452d-8ff6-418a4cfd862'	System	17 Aug 2020 00:08:47
User entered 'None (0)'	System	17 Aug 2020 00:08:47

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:12

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-16T19:08:21', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '51518870-e27c-452d-8ff6-418a4cfd862'	System	17 Aug 2020 00:08:47
User entered 'None (0)'	System	17 Aug 2020 00:08:47

**US3812098**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:56:12**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-16T19:08:23', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '51518870-e27c-452d-8ff6-418a4cfd862'	System	17 Aug 2020 00:08:47
User entered 'None (0)'	System	17 Aug 2020 00:08:47

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:12

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)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-16T19:08:28', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '51518870-e27c-452d-8ff6-418a4cfd862'	System	17 Aug 2020 00:08:47
User entered 'No (N)'	System	17 Aug 2020 00:08:47

**US3812098**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-16T19:08:34', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '51518870-e27c-452d-8ff6-418a4cfd862'	System	17 Aug 2020 00:08:47
User entered '16 Aug 2020 19:08'	System	17 Aug 2020 00:08:47

US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 15:07:32



US3812098

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Angie Kean (b) (4)	18 Aug 2020 18:27:45

**US3812098**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '17 Aug 2020'	Angie Kean (b) (4)	18 Aug 2020 18:27:45

US3812098

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Contact Made (CONTACT MADE)'	Angie Kean (b) (4)	18 Aug 2020 18:27:45

US3812098

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:12

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered empty.	Angie Kean (b) (4)	18 Aug 2020 18:27:45

US3812098

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Karen Knapp (b) (4)	03 Sep 2020 14:22:04

**US3812098**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:56:12**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'I'	System	03 Sep 2020 14:22:04

**US3812098**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:56:12**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Heather Cherniawski	10 Sep 2020 14:05:17



**US3812098**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '25 Aug 2020'	Heather Cherniawski	10 Sep 2020 14:05:17

US3812098

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Contact Made (CONTACT MADE)'	Heather Cherniawski	10 Sep 2020 14:05:17

**US3812098**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:56:12**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered empty.	Heather Cherniawski (b) (4)	10 Sep 2020 14:05:17

US3812098

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Heather Cherniawski	10 Sep 2020 14:05:23

US3812098

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'I'	System	10 Sep 2020 14:05:23

**US3812098**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:56:12**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Heather Cherniawski	10 Sep 2020 14:05:47

**US3812098**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:56:12**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '01 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	10 Nov 2020 17:45:27
User entered '1 Sep 2020'	(b) (4)	
	Heather Cherniawski	10 Sep 2020 14:05:47
	(b) (4)	

US3812098

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Contact Made (CONTACT MADE)'	Heather Cherniawski	10 Sep 2020 14:05:47



**US3812098**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:56:12**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered empty.	Heather Cherniawski (b) (4)	10 Sep 2020 14:05:47

US3812098

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Heather Cherniawski	10 Sep 2020 14:05:56

**US3812098**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:56:12**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'I'	System	10 Sep 2020 14:05:56

US3812098

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Heather Cherniawski	10 Sep 2020 14:06:11

US3812098

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:12

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '10 Sep 2020'	Heather Cherniawski	10 Sep 2020 14:06:11

US3812098

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:12

[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 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Clinic (Clinic)'	Heather Cherniawski	10 Sep 2020 14:06:11

**US3812098**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:56:12**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'VISIT2'	System	10 Sep 2020 14:06:11

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User accepted default value 'Pre-Dose (PREDOSE)'	Heather Cherniawski (b) (4)	14 Sep 2020 16:08:20



US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:12

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Heather Cherniawski	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '10 Sep 2020'	Heather Cherniawski	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '08:08'	Heather Cherniawski	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered '10 Sep 2020 08:08'	System	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '97.0' F	Heather Cherniawski	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Oral (Oral)'	Heather Cherniawski (b) (4)	14 Sep 2020 16:08:20

**US3812098**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:56:12**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered empty.	Heather Cherniawski (b) (4)	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '60'	Heather Cherniawski (b) (4)	14 Sep 2020 16:08:20



US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'bpm'	System	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '12'	Heather Cherniawski (b) (4)	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'breaths/min'	System	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '140'	Heather Cherniawski (b) (4)	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'mmHg'	System	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '80'	Heather Cherniawski (b) (4)	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'mmHg'	System	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User accepted default value 'Post-Dose (POSTDOSE)'	Heather Cherniawski (b) (4)	14 Sep 2020 16:08:20



US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '10 Sep 2020'	Heather Cherniawski	14 Sep 2020 16:08:20

**US3812098**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '09:08'	Heather Cherniawski	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered '10 Sep 2020 09:08'	System	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '97.7' F	Heather Cherniawski	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Oral (Oral)'	Heather Cherniawski	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered empty.	Heather Cherniawski (b) (4)	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '63'	Heather Cherniawski	14 Sep 2020 16:08:20



**US3812098**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:56:12**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'bpm'	System	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '12'	Heather Cherniawski (b) (4)	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'breaths/min'	System	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '132'	Heather Cherniawski (b) (4)	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'mmHg'	System	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '90'	Heather Cherniawski (b) (4)	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'mmHg'	System	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:56:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'No (N)'	Heather Cherniawski	14 Sep 2020 16:03:36



US3812098

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:56:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered empty.	Heather Cherniawski	14 Sep 2020 16:03:36

US3812098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:56:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Heather Cherniawski	10 Sep 2020 14:06:31

US3812098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:56:12

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered empty.	Heather Cherniawski	10 Sep 2020 14:06:31

US3812098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:56:12

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 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered empty.	Heather Cherniawski (b) (4)	10 Sep 2020 14:06:31

US3812098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:56:12

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 14:06:31

US3812098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:56:12

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '10 Sep 2020'	Heather Cherniawski	10 Sep 2020 14:06:31

US3812098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:56:12

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '08:37'	Heather Cherniawski	10 Sep 2020 14:06:31

US3812098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:56:12

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered '10 Sep 2020 08:37'	System	10 Sep 2020 14:06:31



US3812098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:56:12

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Left Arm (LEFT ARM)'	Heather Cherniawski	10 Sep 2020 14:06:31

US3812098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:56:12

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'ONCE'	System	10 Sep 2020 14:06:31

US3812098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:56:12

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 14:06:31

US3812098

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	14 Sep 2020 16:04:24

US3812098

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '10 Sep 2020'	Heather Cherniawski	14 Sep 2020 16:04:24

US3812098

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '08:24'	Heather Cherniawski	14 Sep 2020 16:04:24

**US3812098**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:56:12**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered '10 Sep 2020 08:24'	System	14 Sep 2020 16:04:24

US3812098

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:56:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '10 Sep 2020'	Heather Cherniawski (b) (4)	14 Sep 2020 16:04:45



**US3812098**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:56:12**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Heather Cherniawski (b) (4)	14 Sep 2020 16:04:45

US3812098

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:56:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	14 Sep 2020 16:04:45

**US3812098**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '08:27'	Heather Cherniawski	14 Sep 2020 16:04:45

**US3812098**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:56:12**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered '10 Sep 2020 08:27'	System	14 Sep 2020 16:04:45

**US3812098**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:56:12**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Heather Cherniawski (b) (4)	14 Sep 2020 16:04:45

US3812098

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:56:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'No (N)'	Heather Cherniawski (b) (4)	14 Sep 2020 16:04:45

US3812098

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:56:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered empty.	Heather Cherniawski (b) (4)	14 Sep 2020 16:04:45

**US3812098**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:56:12**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered empty.	System	14 Sep 2020 16:04:45



US3812098

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 03:40:57

**US3812098**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:56:12**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'I'	System	15 Sep 2020 03:40:57

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T09:12:28', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '6f29a702-5b31-4081-95a6-84a6f10ebd80'	System	10 Sep 2020 14:12:59
User entered 'Yes (Y)'	System	10 Sep 2020 14:12:59

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T09:12:40', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '6f29a702-5b31-4081-95a6-84a6f10ebd80' User entered '97.7'	System	10 Sep 2020 14:12:59
	System	10 Sep 2020 14:12:59

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T09:12:47', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '6f29a702-5b31-4081-95a6-84a6f10ebd80' User entered 'No (N)'	System	10 Sep 2020 14:12:59
	System	10 Sep 2020 14:12:59

**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T09:12:57', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '6f29a702-5b31-4081-95a6-84a6f10ebd80' User entered '10 Sep 2020 09:12'	System	10 Sep 2020 14:12:59
	System	10 Sep 2020 14:12:59

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '10 Sep 2020 08:57'	System	10 Sep 2020 14:06:31



US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '10 Sep 2020 11:27'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T17:02:21', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '87fad030-1f04-41ae-93a7-7330f49b3d5f' User entered 'Yes (Y)'	System	10 Sep 2020 22:02:55
	System	10 Sep 2020 22:02:55

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T17:02:26', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '87fad030-1f04-41ae-93a7-7330f49b3d5f' User entered '99.8'	System	10 Sep 2020 22:02:55
	System	10 Sep 2020 22:02:55

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T17:02:32', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '87fad030-1f04-41ae-93a7-7330f49b3d5f' User entered 'Yes (Y)'	System	10 Sep 2020 22:02:55
	System	10 Sep 2020 22:02:55

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'subject was contacted' (Site from System).	(b) (4), (b) (6)	23 Sep 2020 13:27:05
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Karen Knapp (b) (4)	20 Sep 2020 17:30:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T17:02:40', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '87fad030-1f04-41ae-93a7-7330f49b3d5f'	(b) (4)	
User entered '1'	System	10 Sep 2020 22:02:55
	System	10 Sep 2020 22:02:55
	System	10 Sep 2020 22:02:55

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T17:02:40', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '87fad030-1f04-41ae-93a7-7330f49b3d5f' User entered '0'	System	10 Sep 2020 22:02:55
	System	10 Sep 2020 22:02:55

**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T17:02:51', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '87fad030-1f04-41ae-93a7-7330f49b3d5f' User entered '10 Sep 2020 17:02'	System	10 Sep 2020 22:02:55
	System	10 Sep 2020 22:02:55



US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '10 Sep 2020 12:22'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 2'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:56:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-11T15:13:15', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '40534057-e04d-47ae-ae93-d2ab1b2ca1ac' User entered 'Yes (Y)'	System	11 Sep 2020 20:13:57
	System	11 Sep 2020 20:13:57

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:56:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-11T15:13:24', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '40534057-e04d-47ae-ae93-d2ab1b2ca1ac' User entered '98.1'	System	11 Sep 2020 20:13:57
	System	11 Sep 2020 20:13:57

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-11T15:13:30', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '40534057-e04d-47ae-ae93-d2ab1b2ca1ac'	System	11 Sep 2020 20:13:57
User entered 'Yes (Y)'	System	11 Sep 2020 20:13:57

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'subject was contacted' (Site from System).	(b) (4), (b) (6)	23 Sep 2020 13:27:16
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Karen Knapp (b) (4)	20 Sep 2020 17:31:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-11T15:13:41', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '40534057-e04d-47ae-ae93-d2ab1b2ca1ac'	(b) (4)	
User entered '1'	System	11 Sep 2020 20:13:57
	System	11 Sep 2020 20:13:57
	System	11 Sep 2020 20:13:57

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:56:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-11T15:13:41', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '40534057-e04d-47ae-ae93-d2ab1b2ca1ac' User entered '0'	System	11 Sep 2020 20:13:57
	System	11 Sep 2020 20:13:57



**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-11T15:13:52', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '40534057-e04d-47ae-ae93-d2ab1b2ca1ac'	System	11 Sep 2020 20:13:57
User entered '11 Sep 2020 15:13'	System	11 Sep 2020 20:13:57

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 3'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:56:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T10:08:27', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '445c806f-b982-421f-bed6-bc1195baee1a' User entered 'Yes (Y)'	System	13 Sep 2020 15:09:09
	System	13 Sep 2020 15:09:09

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:56:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T10:08:41', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '445c806f-b982-421f-bed6-bc1195baee1a' User entered '98.4'	System	13 Sep 2020 15:09:09
	System	13 Sep 2020 15:09:09

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T10:08:47', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '445c806f-b982-421f-bed6-bc1195baee1a' User entered 'No (N)'	System	13 Sep 2020 15:09:09
	System	13 Sep 2020 15:09:09

**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T10:08:52', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '445c806f-b982-421f-bed6-bc1195baee1a' User entered '13 Sep 2020 10:08'	System	13 Sep 2020 15:09:09
	System	13 Sep 2020 15:09:09



US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 4'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:56:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T14:41:51', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'efea882f-ac67-4d1e-bbbb-bff8b4c14d13' User entered 'Yes (Y)'	System	13 Sep 2020 19:42:18
	System	13 Sep 2020 19:42:18

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:56:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T14:41:58', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'efea882f-ac67-4d1e-bbbb-bff8b4c14d13' User entered '98.9'	System	13 Sep 2020 19:42:18
	System	13 Sep 2020 19:42:18

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T14:42:02', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'efea882f-ac67-4d1e-bbbb-bff8b4c14d13'	System	13 Sep 2020 19:42:18
User entered 'No (N)'	System	13 Sep 2020 19:42:18

**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T14:42:14', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'efea882f-ac67-4d1e-bbbb-bff8b4c14d13'	System	13 Sep 2020 19:42:18
User entered '13 Sep 2020 14:42'	System	13 Sep 2020 19:42:18

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 14:06:31



US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 5'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:56:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-14T18:20:18', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '1f875aa6-16b7-458b-9155-b96eb399496a' User entered 'Yes (Y)'	System	14 Sep 2020 23:20:37
	System	14 Sep 2020 23:20:37

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:56:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-14T18:20:25', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '1f875aa6-16b7-458b-9155-b96eb399496a' User entered '98.2'	System	14 Sep 2020 23:20:37
	System	14 Sep 2020 23:20:37

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-14T18:20:30', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '1f875aa6-16b7-458b-9155-b96eb399496a' User entered 'No (N)'	System	14 Sep 2020 23:20:37
	System	14 Sep 2020 23:20:37

**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-14T18:20:35', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '1f875aa6-16b7-458b-9155-b96eb399496a' User entered '14 Sep 2020 18:20'	System	14 Sep 2020 23:20:37
	System	14 Sep 2020 23:20:37

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 14:06:31



US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 6'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:56:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-15T18:38:19', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e7c2fd79-0658-4edc-9976-34dbba97aea3' User entered 'Yes (Y)'	System	15 Sep 2020 23:38:45
	System	15 Sep 2020 23:38:45

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:56:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-15T18:38:28', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e7c2fd79-0658-4edc-9976-34dbba97aea3' User entered '98.7'	System	15 Sep 2020 23:38:45
	System	15 Sep 2020 23:38:45

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-15T18:38:35', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e7c2fd79-0658-4edc-9976-34dbba97aea3'	System	15 Sep 2020 23:38:45
User entered 'No (N)'	System	15 Sep 2020 23:38:45

**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-15T18:38:42', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e7c2fd79-0658-4edc-9976-34dbba97aea3' User entered '15 Sep 2020 18:38'	System	15 Sep 2020 23:38:45
	System	15 Sep 2020 23:38:45

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 7'	System	10 Sep 2020 14:06:31



US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:56:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-16T17:49:39', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'f21e033a-f3fe-442a-ab8a-6e710c816bca' User entered 'Yes (Y)'	System	16 Sep 2020 22:50:06
	System	16 Sep 2020 22:50:06

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:56:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-16T17:49:44', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'f21e033a-f3fe-442a-ab8a-6e710c816bca' User entered '98.3'	System	16 Sep 2020 22:50:06
	System	16 Sep 2020 22:50:06

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-16T17:49:57', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'f21e033a-f3fe-442a-ab8a-6e710c816bca' User entered 'No (N)'	System	16 Sep 2020 22:50:06
	System	16 Sep 2020 22:50:06

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:56:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-16T17:50:03', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'f21e033a-f3fe-442a-ab8a-6e710c816bca' User entered '16 Sep 2020 17:50'	System	16 Sep 2020 22:50:06
	System	16 Sep 2020 22:50:06

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T09:13:08', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9f8f3b80-4fe0-4230-a95e-b9cfcdc7746b' User entered 'None (1)'	System	10 Sep 2020 14:13:39
	System	10 Sep 2020 14:13:39



US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T09:13:14', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9f8f3b80-4fe0-4230-a95e-b9cfcdc7746b' User entered 'No (N)'	System	10 Sep 2020 14:13:39
	System	10 Sep 2020 14:13:39

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T09:13:19', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9f8f3b80-4fe0-4230-a95e-b9cfcdc7746b' User entered 'No (N)'	System	10 Sep 2020 14:13:39
	System	10 Sep 2020 14:13:39

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T09:13:25', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9f8f3b80-4fe0-4230-a95e-b9cfc7746b'	System	10 Sep 2020 14:13:39
User entered 'None (1)'	System	10 Sep 2020 14:13:39

**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T09:13:36', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9f8f3b80-4fe0-4230-a95e-b9cfcdc7746b' User entered '10 Sep 2020 09:13'	System	10 Sep 2020 14:13:39
	System	10 Sep 2020 14:13:39

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '10 Sep 2020 08:57'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '10 Sep 2020 11:27'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T17:03:12', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a6a1fc69-48e7-46c9-a8e9-4fd31682e884'	System	10 Sep 2020 22:04:10
User entered 'Does not interfere with activity (2)'	System	10 Sep 2020 22:04:10



US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T17:03:16', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a6a1fc69-48e7-46c9-a8e9-4fd31682e884' User entered 'No (N)'	System	10 Sep 2020 22:04:10
	System	10 Sep 2020 22:04:10

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T17:03:28', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a6a1fc69-48e7-46c9-a8e9-4fd31682e884' User entered 'No (N)'	System	10 Sep 2020 22:04:10
	System	10 Sep 2020 22:04:10

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T17:03:56', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a6a1fc69-48e7-46c9-a8e9-4fd31682e884'	System	10 Sep 2020 22:04:10
User entered 'None (1)'	System	10 Sep 2020 22:04:10

**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T17:04:06', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a6a1fc69-48e7-46c9-a8e9-4fd31682e884'	System	10 Sep 2020 22:04:10
User entered '10 Sep 2020 17:04'	System	10 Sep 2020 22:04:10

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '10 Sep 2020 12:22'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 2'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:56:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-11T15:14:03', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'd22625f8-a851-4318-837e-b55ce853a9ee'	System	11 Sep 2020 20:14:29
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 20:14:29



US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:56:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-11T15:14:08', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'd22625f8-a851-4318-837e-b55ce853a9ee'	System	11 Sep 2020 20:14:29
User entered 'No (N)'	System	11 Sep 2020 20:14:29

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-11T15:14:12', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'd22625f8-a851-4318-837e-b55ce853a9ee' User entered 'No (N)'	System	11 Sep 2020 20:14:29
	System	11 Sep 2020 20:14:29

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:56:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-11T15:14:16', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'd22625f8-a851-4318-837e-b55ce853a9ee' User entered 'None (1)'	System	11 Sep 2020 20:14:29
	System	11 Sep 2020 20:14:29

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:56:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-11T15:14:24', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'd22625f8-a851-4318-837e-b55ce853a9ee'	System	11 Sep 2020 20:14:29
User entered '11 Sep 2020 15:14'	System	11 Sep 2020 20:14:29

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 3'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:56:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T10:08:59', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '7bfa7f1d-5154-4eb9-969f-02246920354c'	System	13 Sep 2020 15:09:36
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 15:09:36



US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:56:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T10:09:03', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '7bfa7f1d-5154-4eb9-969f-02246920354c' User entered 'No (N)'	System	13 Sep 2020 15:09:36
	System	13 Sep 2020 15:09:36

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T10:09:06', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '7bfa7f1d-5154-4eb9-969f-02246920354c' User entered 'No (N)'	System	13 Sep 2020 15:09:36
	System	13 Sep 2020 15:09:36

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:56:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T10:09:09', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '7bfa7f1d-5154-4eb9-969f-02246920354c' User entered 'None (1)'	System	13 Sep 2020 15:09:36
	System	13 Sep 2020 15:09:36

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:56:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T10:09:18', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '7bfa7f1d-5154-4eb9-969f-02246920354c' User entered '13 Sep 2020 10:09'	System	13 Sep 2020 15:09:36
	System	13 Sep 2020 15:09:36

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 4'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:56:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T14:42:22', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e25f5e3c-4c43-407c-834b-5851ff3f34ab' User entered 'None (1)'	System	13 Sep 2020 19:42:49
	System	13 Sep 2020 19:42:49



US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:56:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T14:42:27', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e25f5e3c-4c43-407c-834b-5851ff3f34ab' User entered 'No (N)'	System	13 Sep 2020 19:42:49
	System	13 Sep 2020 19:42:49

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T14:42:31', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e25f5e3c-4c43-407c-834b-5851ff3f34ab' User entered 'No (N)'	System	13 Sep 2020 19:42:49
	System	13 Sep 2020 19:42:49

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:56:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T14:42:35', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e25f5e3c-4c43-407c-834b-5851ff3f34ab' User entered 'None (1)'	System	13 Sep 2020 19:42:49
	System	13 Sep 2020 19:42:49

**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T14:42:47', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e25f5e3c-4c43-407c-834b-5851ff3f34ab' User entered '13 Sep 2020 14:42'	System	13 Sep 2020 19:42:49
	System	13 Sep 2020 19:42:49

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 5'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:56:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-14T18:20:41', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ee46c763-a1d1-4d7c-b61d-33b0504a9b93'	System	14 Sep 2020 23:21:11
User entered 'None (1)'	System	14 Sep 2020 23:21:11



US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:56:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-14T18:20:46', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ee46c763-a1d1-4d7c-b61d-33b0504a9b93'	System	14 Sep 2020 23:21:11
User entered 'No (N)'	System	14 Sep 2020 23:21:11

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-14T18:20:51', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ee46c763-a1d1-4d7c-b61d-33b0504a9b93'	System	14 Sep 2020 23:21:11
User entered 'No (N)'	System	14 Sep 2020 23:21:11

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:56:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-14T18:21:02', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ee46c763-a1d1-4d7c-b61d-33b0504a9b93'	System	14 Sep 2020 23:21:11
User entered 'None (1)'	System	14 Sep 2020 23:21:11

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:56:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-14T18:21:08', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ee46c763-a1d1-4d7c-b61d-33b0504a9b93'	System	14 Sep 2020 23:21:11
User entered '14 Sep 2020 18:21'	System	14 Sep 2020 23:21:11

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 6'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:56:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-15T18:38:53', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '22740705-d95e-46f6-b314-26848e84ca92'	System	15 Sep 2020 23:39:34
User entered 'None (1)'	System	15 Sep 2020 23:39:34



US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:56:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-15T18:38:57', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '22740705-d95e-46f6-b314-26848e84ca92'	System	15 Sep 2020 23:39:34
User entered 'No (N)'	System	15 Sep 2020 23:39:34

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-15T18:38:59', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '22740705-d95e-46f6-b314-26848e84ca92' User entered 'No (N)'	System	15 Sep 2020 23:39:34
	System	15 Sep 2020 23:39:34

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:56:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-15T18:39:02', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '22740705-d95e-46f6-b314-26848e84ca92'	System	15 Sep 2020 23:39:34
User entered 'None (1)'	System	15 Sep 2020 23:39:34

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:56:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-15T18:39:31', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '22740705-d95e-46f6-b314-26848e84ca92'	System	15 Sep 2020 23:39:34
User entered '15 Sep 2020 18:39'	System	15 Sep 2020 23:39:34

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 7'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:56:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-16T17:50:08', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '950d0f87-c8e6-4049-a6e7-676a3011920e' User entered 'None (1)'	System	16 Sep 2020 22:50:35
	System	16 Sep 2020 22:50:35



US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:56:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-16T17:50:13', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '950d0f87-c8e6-4049-a6e7-676a3011920e' User entered 'No (N)'	System	16 Sep 2020 22:50:35
	System	16 Sep 2020 22:50:35

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-16T17:50:17', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '950d0f87-c8e6-4049-a6e7-676a3011920e' User entered 'No (N)'	System	16 Sep 2020 22:50:35
	System	16 Sep 2020 22:50:35

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:56:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-16T17:50:21', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '950d0f87-c8e6-4049-a6e7-676a3011920e' User entered 'None (1)'	System	16 Sep 2020 22:50:35
	System	16 Sep 2020 22:50:35

**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-16T17:50:32', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '950d0f87-c8e6-4049-a6e7-676a3011920e' User entered '16 Sep 2020 17:50'	System	16 Sep 2020 22:50:35
	System	16 Sep 2020 22:50:35

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T09:13:44', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ff918b9a-03a3-4bd5-b6d6-bbac0a2875ec' User entered 'None (0)'	System	10 Sep 2020 14:14:08
	System	10 Sep 2020 14:14:08



US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T09:13:47', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ff918b9a-03a3-4bd5-b6d6-bbac0a2875ec' User entered 'None (0)'	System	10 Sep 2020 14:14:08
	System	10 Sep 2020 14:14:08

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T09:13:50', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ff918b9a-03a3-4bd5-b6d6-bbac0a2875ec' User entered 'None (0)'	System	10 Sep 2020 14:14:08
	System	10 Sep 2020 14:14:08

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T09:13:53', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ff918b9a-03a3-4bd5-b6d6-bbac0a2875ec' User entered 'None (0)'	System	10 Sep 2020 14:14:08
	System	10 Sep 2020 14:14:08

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T09:13:56', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ff918b9a-03a3-4bd5-b6d6-bbac0a2875ec' User entered 'None (0)'	System	10 Sep 2020 14:14:08
	System	10 Sep 2020 14:14:08

**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:56:12**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T09:13:58', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ff918b9a-03a3-4bd5-b6d6-bbac0a2875ec' User entered 'None (0)'	System	10 Sep 2020 14:14:08
	System	10 Sep 2020 14:14:08

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

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)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T09:14:01', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ff918b9a-03a3-4bd5-b6d6-bbac0a2875ec' User entered 'No (N)'	System	10 Sep 2020 14:14:08
	System	10 Sep 2020 14:14:08

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T09:14:06', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ff918b9a-03a3-4bd5-b6d6-bbac0a2875ec' User entered '10 Sep 2020 09:14'	System	10 Sep 2020 14:14:08
	System	10 Sep 2020 14:14:08

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '10 Sep 2020 08:57'	System	10 Sep 2020 14:06:31



US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '10 Sep 2020 11:27'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T17:04:14', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '29ae7cf9-cff6-4bd4-bd68-c2dcfd7b6009' User entered 'None (0)'	System	10 Sep 2020 22:05:19
	System	10 Sep 2020 22:05:19

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T17:04:19', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '29ae7cf9-cff6-4bd4-bd68-c2dcfd7b6009'	System	10 Sep 2020 22:05:19
User entered 'No interference with activity (1)'	System	10 Sep 2020 22:05:19

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T17:04:28', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '29ae7cf9-cff6-4bd4-bd68-c2dcfd7b6009' User entered 'None (0)'	System	10 Sep 2020 22:05:19
	System	10 Sep 2020 22:05:19

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T17:04:34', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '29ae7cf9-cff6-4bd4-bd68-c2dcfd7b6009' User entered 'None (0)'	System	10 Sep 2020 22:05:19
	System	10 Sep 2020 22:05:19

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T17:04:38', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '29ae7cf9-cff6-4bd4-bd68-c2dcfd7b6009' User entered 'None (0)'	System	10 Sep 2020 22:05:19
	System	10 Sep 2020 22:05:19

**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:56:12**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T17:04:42', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '29ae7cf9-cff6-4bd4-bd68-c2dcfd7b6009' User entered 'None (0)'	System	10 Sep 2020 22:05:19
	System	10 Sep 2020 22:05:19



US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:12

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)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T17:04:50', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '29ae7cf9-cff6-4bd4-bd68-c2dcfd7b6009'	System	10 Sep 2020 22:05:19
User entered 'No (N)'	System	10 Sep 2020 22:05:19

**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T17:05:16', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '29ae7cf9-cff6-4bd4-bd68-c2dcfd7b6009' User entered '10 Sep 2020 17:05'	System	10 Sep 2020 22:05:19
	System	10 Sep 2020 22:05:19

**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '10 Sep 2020 12:22'	System	10 Sep 2020 14:06:31

**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 2'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:12

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-11T15:14:31', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '745b3658-8686-4a40-8fab-2787703ea398' User entered 'None (0)'	System	11 Sep 2020 20:15:42
	System	11 Sep 2020 20:15:42

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:12

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-11T15:14:48', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '745b3658-8686-4a40-8fab-2787703ea398'	System	11 Sep 2020 20:15:42
User entered 'Some interference with activity (2)'	System	11 Sep 2020 20:15:42

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:12

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-11T15:14:53', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '745b3658-8686-4a40-8fab-2787703ea398' User entered 'None (0)'	System	11 Sep 2020 20:15:42
	System	11 Sep 2020 20:15:42



US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:12

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-11T15:14:57', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '745b3658-8686-4a40-8fab-2787703ea398' User entered 'None (0)'	System	11 Sep 2020 20:15:42
	System	11 Sep 2020 20:15:42

**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:56:12**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-11T15:15:01', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '745b3658-8686-4a40-8fab-2787703ea398' User entered 'None (0)'	System	11 Sep 2020 20:15:42
	System	11 Sep 2020 20:15:42

**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:56:12**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-11T15:15:07', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '745b3658-8686-4a40-8fab-2787703ea398'	System	11 Sep 2020 20:15:42
User entered 'No interference with activity (1)'	System	11 Sep 2020 20:15:42

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:12

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)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-11T15:15:12', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '745b3658-8686-4a40-8fab-2787703ea398'	System	11 Sep 2020 20:15:42
User entered 'No (N)'	System	11 Sep 2020 20:15:42

**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-11T15:15:38', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '745b3658-8686-4a40-8fab-2787703ea398'	System	11 Sep 2020 20:15:42
User entered '11 Sep 2020 15:15'	System	11 Sep 2020 20:15:42

**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 3'	System	10 Sep 2020 14:06:31



US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:12

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T10:09:24', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'd77240ab-945e-4575-8eda-d0afb16d6836' User entered 'None (0)'	System	13 Sep 2020 15:09:50
	System	13 Sep 2020 15:09:50

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:12

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T10:09:26', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'd77240ab-945e-4575-8eda-d0afb16d6836' User entered 'None (0)'	System	13 Sep 2020 15:09:50
	System	13 Sep 2020 15:09:50

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:12

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T10:09:29', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'd77240ab-945e-4575-8eda-d0afb16d6836' User entered 'None (0)'	System	13 Sep 2020 15:09:50
	System	13 Sep 2020 15:09:50

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:12

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T10:09:31', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'd77240ab-945e-4575-8eda-d0afb16d6836' User entered 'None (0)'	System	13 Sep 2020 15:09:50
	System	13 Sep 2020 15:09:50

**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:56:12**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T10:09:34', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'd77240ab-945e-4575-8eda-d0afb16d6836' User entered 'None (0)'	System	13 Sep 2020 15:09:50
	System	13 Sep 2020 15:09:50

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:12

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T10:09:37', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'd77240ab-945e-4575-8eda-d0afb16d6836' User entered 'None (0)'	System	13 Sep 2020 15:09:50
	System	13 Sep 2020 15:09:50

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:12

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)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T10:09:43', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'd77240ab-945e-4575-8eda-d0afb16d6836' User entered 'No (N)'	System	13 Sep 2020 15:09:50
	System	13 Sep 2020 15:09:50

**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T10:09:48', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'd77240ab-945e-4575-8eda-d0afb16d6836' User entered '13 Sep 2020 10:09'	System	13 Sep 2020 15:09:50
	System	13 Sep 2020 15:09:50



**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 14:06:31

**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 4'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:12

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T14:42:52', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9835ef65-5983-41c9-aa27-cd0f05136722' User entered 'None (0)'	System	13 Sep 2020 19:43:27
	System	13 Sep 2020 19:43:27

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:12

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T14:42:56', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9835ef65-5983-41c9-aa27-cd0f05136722' User entered 'None (0)'	System	13 Sep 2020 19:43:27
	System	13 Sep 2020 19:43:27

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:12

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T14:42:59', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9835ef65-5983-41c9-aa27-cd0f05136722' User entered 'None (0)'	System	13 Sep 2020 19:43:27
	System	13 Sep 2020 19:43:27

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:12

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T14:43:02', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9835ef65-5983-41c9-aa27-cd0f05136722' User entered 'None (0)'	System	13 Sep 2020 19:43:27
	System	13 Sep 2020 19:43:27

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:12

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T14:43:04', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9835ef65-5983-41c9-aa27-cd0f05136722' User entered 'None (0)'	System	13 Sep 2020 19:43:27
	System	13 Sep 2020 19:43:27



US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:12

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T14:43:07', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9835ef65-5983-41c9-aa27-cd0f05136722' User entered 'None (0)'	System	13 Sep 2020 19:43:27
	System	13 Sep 2020 19:43:27

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:12

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)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T14:43:11', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9835ef65-5983-41c9-aa27-cd0f05136722'	System	13 Sep 2020 19:43:27
User entered 'No (N)'	System	13 Sep 2020 19:43:27

**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T14:43:25', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9835ef65-5983-41c9-aa27-cd0f05136722' User entered '13 Sep 2020 14:43'	System	13 Sep 2020 19:43:27
	System	13 Sep 2020 19:43:27

**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 14:06:31

**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 5'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:12

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-14T18:21:14', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '435f6f56-30bf-4649-b0c4-f2d86723b66b' User entered 'None (0)'	System	14 Sep 2020 23:21:54
	System	14 Sep 2020 23:21:54

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:12

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-14T18:21:17', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '435f6f56-30bf-4649-b0c4-f2d86723b66b' User entered 'None (0)'	System	14 Sep 2020 23:21:54
	System	14 Sep 2020 23:21:54



US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:12

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-14T18:21:20', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '435f6f56-30bf-4649-b0c4-f2d86723b66b' User entered 'None (0)'	System	14 Sep 2020 23:21:54
	System	14 Sep 2020 23:21:54

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:12

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-14T18:21:25', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '435f6f56-30bf-4649-b0c4-f2d86723b66b' User entered 'None (0)'	System	14 Sep 2020 23:21:54
	System	14 Sep 2020 23:21:54

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:12

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-14T18:21:29', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '435f6f56-30bf-4649-b0c4-f2d86723b66b' User entered 'None (0)'	System	14 Sep 2020 23:21:54
	System	14 Sep 2020 23:21:54

**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:56:12**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-14T18:21:32', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '435f6f56-30bf-4649-b0c4-f2d86723b66b' User entered 'None (0)'	System	14 Sep 2020 23:21:54
	System	14 Sep 2020 23:21:54

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:12

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)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-14T18:21:38', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '435f6f56-30bf-4649-b0c4-f2d86723b66b' User entered 'No (N)'	System	14 Sep 2020 23:21:54
	System	14 Sep 2020 23:21:54

**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-14T18:21:51', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '435f6f56-30bf-4649-b0c4-f2d86723b66b' User entered '14 Sep 2020 18:21'	System	14 Sep 2020 23:21:54
	System	14 Sep 2020 23:21:54

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 14:06:31



US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 6'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:12

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-15T18:39:36', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'fbce7665-3fb9-4dd1-bbbb-37e288cbc098' User entered 'None (0)'	System	15 Sep 2020 23:40:17
	System	15 Sep 2020 23:40:17

**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:56:12**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-15T18:39:39', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'fbce7665-3fb9-4dd1-bbbb-37e288cbc098' User entered 'None (0)'	System	15 Sep 2020 23:40:17
	System	15 Sep 2020 23:40:17

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:12

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-15T18:39:44', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'fbce7665-3fb9-4dd1-bbbb-37e288cbc098' User entered 'None (0)'	System	15 Sep 2020 23:40:17
	System	15 Sep 2020 23:40:17

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:12

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-15T18:39:48', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'fbce7665-3fb9-4dd1-bbbb-37e288cbc098' User entered 'None (0)'	System	15 Sep 2020 23:40:17
	System	15 Sep 2020 23:40:17

**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:56:12**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-15T18:39:52', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'fbce7665-3fb9-4dd1-bbbb-37e288cbc098' User entered 'None (0)'	System	15 Sep 2020 23:40:17
	System	15 Sep 2020 23:40:17

**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:56:12**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-15T18:39:54', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'fbce7665-3fb9-4dd1-bbbb-37e288cbc098' User entered 'None (0)'	System	15 Sep 2020 23:40:17
	System	15 Sep 2020 23:40:17

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:12

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)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-15T18:40:01', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'fbce7665-3fb9-4dd1-bbbb-37e288cbc098'	System	15 Sep 2020 23:40:17
User entered 'No (N)'	System	15 Sep 2020 23:40:17



**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-15T18:40:12', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'fbce7665-3fb9-4dd1-bbbb-37e288cbc098'	System	15 Sep 2020 23:40:17
User entered '15 Sep 2020 18:40'	System	15 Sep 2020 23:40:17

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 14:06:31

**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 7'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:12

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-16T17:50:37', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '0b66e864-de8f-484a-b615-ac05466995e5' User entered 'None (0)'	System	16 Sep 2020 22:51:08
	System	16 Sep 2020 22:51:08

**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:56:12**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-16T17:50:40', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '0b66e864-de8f-484a-b615-ac05466995e5' User entered 'None (0)'	System	16 Sep 2020 22:51:08
	System	16 Sep 2020 22:51:08

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:12

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-16T17:50:45', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '0b66e864-de8f-484a-b615-ac05466995e5' User entered 'None (0)'	System	16 Sep 2020 22:51:08
	System	16 Sep 2020 22:51:08

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:12

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-16T17:50:50', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '0b66e864-de8f-484a-b615-ac05466995e5' User entered 'None (0)'	System	16 Sep 2020 22:51:08
	System	16 Sep 2020 22:51:08



US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:12

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-16T17:50:53', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '0b66e864-de8f-484a-b615-ac05466995e5' User entered 'None (0)'	System	16 Sep 2020 22:51:08
	System	16 Sep 2020 22:51:08

**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:56:12**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-16T17:50:55', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '0b66e864-de8f-484a-b615-ac05466995e5' User entered 'None (0)'	System	16 Sep 2020 22:51:08
	System	16 Sep 2020 22:51:08

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:12

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)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-16T17:50:59', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '0b66e864-de8f-484a-b615-ac05466995e5' User entered 'No (N)'	System	16 Sep 2020 22:51:08
	System	16 Sep 2020 22:51:08

**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-16T17:51:05', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '0b66e864-de8f-484a-b615-ac05466995e5' User entered '16 Sep 2020 17:51'	System	16 Sep 2020 22:51:08
	System	16 Sep 2020 22:51:08

**US3812098**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:56:12**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

**US3812098**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:56:12**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Karen Knapp (b) (4)	17 Sep 2020 18:05:00

**US3812098**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '17 Sep 2020'	Karen Knapp (b) (4)	17 Sep 2020 18:05:00



US3812098

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	17 Sep 2020 18:05:00

US3812098

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:12

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered empty.	Karen Knapp (b) (4)	17 Sep 2020 18:05:00

US3812098

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Karen Knapp (b) (4)	17 Sep 2020 18:05:06

**US3812098**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:56:12**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'I'	System	17 Sep 2020 18:05:06

**US3812098**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:56:12**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Karen Knapp (b) (4)	24 Sep 2020 19:03:18

US3812098

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '24 Sep 2020'	Karen Knapp (b) (4)	24 Sep 2020 19:03:18

**US3812098**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:56:12**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	24 Sep 2020 19:03:18

US3812098

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:12

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered empty.	Karen Knapp (b) (4)	24 Sep 2020 19:03:18



US3812098

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Karen Knapp (b) (4)	24 Sep 2020 19:03:23

US3812098

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'I'	System	24 Sep 2020 19:03:23

**US3812098**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:56:12**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Karen Knapp (b) (4)	01 Oct 2020 18:42:44

**US3812098**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:56:12**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '01 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	10 Nov 2020 17:46:13
User entered '1 Oct 2020'	(b) (4)	
	Karen Knapp (b) (4)	01 Oct 2020 18:42:44
	(b) (4)	

US3812098

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	01 Oct 2020 18:42:44

**US3812098**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:56:12**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered empty.	Karen Knapp (b) (4)	01 Oct 2020 18:42:44

US3812098

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Karen Knapp (b) (4)	01 Oct 2020 18:42:48

**US3812098**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:56:12**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'I'	System	01 Oct 2020 18:42:48



US3812098

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:42:00
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	09 Oct 2020 17:43:58

US3812098

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:42:00
User entered '09 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	10 Nov 2020 17:46:30
User entered '9 Oct 2020'	(b) (4)	
	Breanna Galibert (b) (4)	09 Oct 2020 17:43:58
	(b) (4)	

US3812098

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:12

[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 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:42:00
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	09 Oct 2020 17:43:58

**US3812098**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:56:12**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'VISIT3'	System	09 Oct 2020 17:43:58

US3812098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:42:00
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	09 Oct 2020 17:44:20

US3812098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:42:00
User entered '09 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	10 Nov 2020 17:46:42
User entered '9 Oct 2020'	(b) (4)	
	Breanna Galibert (b) (4)	09 Oct 2020 17:44:20
	(b) (4)	

US3812098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:42:00
User entered '09:50'	Breanna Galibert (b) (4)	09 Oct 2020 17:44:20

**US3812098**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered '09 Oct 2020 09:50'	System	10 Nov 2020 17:46:42
User entered '9 Oct 2020 09:50'	System	09 Oct 2020 17:44:20



US3812098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:42:00
User entered '97.5' F	Breanna Galibert (b) (4)	09 Oct 2020 17:44:20

US3812098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:42:00
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	09 Oct 2020 17:44:20

US3812098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:42:00
User entered empty.	Breanna Galibert (b) (4)	09 Oct 2020 17:44:20

US3812098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:42:00
User entered '76'	Breanna Galibert (b) (4)	09 Oct 2020 17:44:20

**US3812098**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:56:12**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'bpm'	System	09 Oct 2020 17:44:20

US3812098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:42:00
User entered '17'	Breanna Galibert (b) (4)	09 Oct 2020 17:44:20

US3812098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'breaths/min'	System	09 Oct 2020 17:44:20

US3812098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:42:00
User entered '124'	Breanna Galibert (b) (4)	09 Oct 2020 17:44:20



US3812098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'mmHg'	System	09 Oct 2020 17:44:20

US3812098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:42:00
User entered '74'	Breanna Galibert (b) (4)	09 Oct 2020 17:44:20

US3812098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'mmHg'	System	09 Oct 2020 17:44:20

US3812098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20

US3812098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:12

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20

US3812098

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:56:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:42:00
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	09 Oct 2020 17:44:40

US3812098

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:56:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:42:00
User entered '09 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	10 Nov 2020 17:47:04
User entered '9 Oct 2020'	(b) (4)	
	Breanna Galibert (b) (4)	09 Oct 2020 17:44:40
	(b) (4)	

US3812098

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:42:00
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	09 Oct 2020 17:44:51



US3812098

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:42:00
User entered '09 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	10 Nov 2020 17:47:12
User entered '9 Oct 2020'	(b) (4)	
	Breanna Galibert (b) (4)	09 Oct 2020 17:44:51
	(b) (4)	

US3812098

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:42:00
User entered '10:20'	Breanna Galibert (b) (4)	09 Oct 2020 17:44:51

**US3812098**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:56:12**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered '09 Oct 2020 10:20'	System	10 Nov 2020 17:47:12
User entered '9 Oct 2020 10:20'	System	09 Oct 2020 17:44:51

US3812098

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Karen Knapp (b) (4)	18 Oct 2020 15:37:06

**US3812098**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:56:12**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'I'	System	18 Oct 2020 15:37:06

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 64'	System	10 Aug 2020 15:07:32

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

[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)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-10-14T08:43:49', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '04dc6c0a-e8e3-4a51-9b14-03f4f4329243'	System	14 Oct 2020 13:44:43
User entered 'Yes (Y)'	System	14 Oct 2020 13:44:43

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

Have you been exposed to someone with 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)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-10-14T08:43:59', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '04dc6c0a-e8e3-4a51-9b14-03f4f4329243'	System	14 Oct 2020 13:44:43
User entered 'No (N)'	System	14 Oct 2020 13:44:43



US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-10-14T08:44:13', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '04dc6c0a-e8e3-4a51-9b14-03f4f4329243'	System	14 Oct 2020 13:44:43
User entered 'No (N)'	System	14 Oct 2020 13:44:43

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-10-14T08:44:22', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '04dc6c0a-e8e3-4a51-9b14-03f4f4329243'	System	14 Oct 2020 13:44:43
User entered 'No (N)'	System	14 Oct 2020 13:44:43

**US3812098**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-10-14T08:44:39', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '04dc6c0a-e8e3-4a51-9b14-03f4f4329243' User entered '14 Oct 2020 08:44:39'	System	14 Oct 2020 13:44:43
	System	14 Oct 2020 13:44:43

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered '10 Oct 2020 00:01'	System	10 Aug 2020 15:07:32

**US3812098**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered '14 Oct 2020 23:59'	System	10 Aug 2020 15:07:32

**US3812098**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 71'	System	10 Aug 2020 15:07:32

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

[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)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-10-20T12:13:15', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a18ba5e2-ec39-48e3-bebf-f4ebdb115c8a'	System	20 Oct 2020 17:13:35
User entered 'No (N)'	System	20 Oct 2020 17:13:35

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

Have you been exposed to someone with 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)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-10-20T12:13:20', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a18ba5e2-ec39-48e3-bebf-f4ebdb115c8a'	System	20 Oct 2020 17:13:35
User entered 'No (N)'	System	20 Oct 2020 17:13:35



**US3812098**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-10-20T12:13:29', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a18ba5e2-ec39-48e3-bebf-f4ebdb115c8a' User entered '20 Oct 2020 12:13:29'	System	20 Oct 2020 17:13:35
	System	20 Oct 2020 17:13:35

**US3812098**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered '17 Oct 2020 00:01'	System	10 Aug 2020 15:07:32

**US3812098**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered '21 Oct 2020 23:59'	System	10 Aug 2020 15:07:32

**US3812098**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 78'	System	10 Aug 2020 15:07:32

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

[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)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-10-27T07:26:34', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a6865674-c7e9-4d6f-893c-56b1de9847ff'	System	27 Oct 2020 12:27:00
User entered 'No (N)'	System	27 Oct 2020 12:27:00

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

Have you been exposed to someone with 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)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-10-27T07:26:42', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a6865674-c7e9-4d6f-893c-56b1de9847ff'	System	27 Oct 2020 12:27:00
User entered 'No (N)'	System	27 Oct 2020 12:27:00

**US3812098**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-10-27T07:26:57', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a6865674-c7e9-4d6f-893c-56b1de9847ff' User entered '27 Oct 2020 07:26:57'	System	27 Oct 2020 12:27:00
	System	27 Oct 2020 12:27:00

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered '24 Oct 2020 00:01'	System	10 Aug 2020 15:07:32



**US3812098**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered '28 Oct 2020 23:59'	System	10 Aug 2020 15:07:32

**US3812098**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 92'	System	10 Aug 2020 15:07:32

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

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)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-11-11T08:14:29', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '6d63c9eb-1b4e-4282-baae-89aab71e07e1' User entered 'No (N)'	System	11 Nov 2020 14:14:48
	System	11 Nov 2020 14:14:48

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

Have you been exposed to someone with 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)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-11-11T08:14:37', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '6d63c9eb-1b4e-4282-baae-89aab71e07e1' User entered 'No (N)'	System	11 Nov 2020 14:14:48
	System	11 Nov 2020 14:14:48

**US3812098**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-11-11T08:14:43', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '6d63c9eb-1b4e-4282-baae-89aab71e07e1' User entered '11 Nov 2020 08:14:43'	System	11 Nov 2020 14:14:48
	System	11 Nov 2020 14:14:48

**US3812098**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered '07 Nov 2020 00:01'	System	10 Aug 2020 15:07:32

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered '11 Nov 2020 23:59'	System	10 Aug 2020 15:07:32

**US3812098**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 99'	System	10 Aug 2020 15:07:32



US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

[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)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-11-17T12:54:43', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '3c745204-8cbb-4aae-b95d-379539afd65e' User entered 'No (N)'	System	17 Nov 2020 18:54:59
	System	17 Nov 2020 18:54:59

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

Have you been exposed to someone with 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)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-11-17T12:54:48', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '3c745204-8cbb-4aae-b95d-379539afd65e' User entered 'No (N)'	System	17 Nov 2020 18:54:59
	System	17 Nov 2020 18:54:59

**US3812098**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-11-17T12:54:55', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '3c745204-8cbb-4aae-b95d-379539afd65e' User entered '17 Nov 2020 12:54:55'	System	17 Nov 2020 18:54:59
	System	17 Nov 2020 18:54:59

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered '14 Nov 2020 00:01'	System	10 Aug 2020 15:07:32

**US3812098**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:45
Data entry locked.	System	10 Aug 2020 15:07:32
User entered '18 Nov 2020 23:59'	System	10 Aug 2020 15:07:32

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 16:59:17



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-11-25T06:43:04', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '8b5c668f-0040-463a-bdb0-88bedbbe72cb' User entered 'No (N)'	System	25 Nov 2020 12:43:22
	System	25 Nov 2020 12:43:22

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

Have you been exposed to someone with 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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-11-25T06:43:14', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '8b5c668f-0040-463a-bdb0-88bedbbe72cb' User entered 'No (N)'	System	25 Nov 2020 12:43:22

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-11-25T06:43:20', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '8b5c668f-0040-463a-bdb0-88bedbbe72cb' User entered '25 Nov 2020 06:43:20'	System	25 Nov 2020 12:43:22
	System	25 Nov 2020 12:43:22

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-12-02T17:32:02', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e3dd5d81-9704-4cc8-b746-0346dc216025'	System	02 Dec 2020 23:33:01
User entered 'Yes (Y)'	System	02 Dec 2020 23:33:01



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Have you been exposed to someone with 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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-12-02T17:32:08', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e3dd5d81-9704-4cc8-b746-0346dc216025'	System	02 Dec 2020 23:33:01
User entered 'No (N)'	System	02 Dec 2020 23:33:01

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-12-02T17:32:16', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e3dd5d81-9704-4cc8-b746-0346dc216025'	System	02 Dec 2020 23:33:01
User entered 'No (N)'	System	02 Dec 2020 23:33:01

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-12-02T17:32:41', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e3dd5d81-9704-4cc8-b746-0346dc216025'	System	02 Dec 2020 23:33:01
User entered 'No (N)'	System	02 Dec 2020 23:33:01

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-12-02T17:32:58', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e3dd5d81-9704-4cc8-b746-0346dc216025'	System	02 Dec 2020 23:33:01
User entered '02 Dec 2020 17:32:58'	System	02 Dec 2020 23:33:01

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-12-11T15:40:12', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9003ab2d-e4da-42b2-a9bd-9d01329956dd'	System	11 Dec 2020 21:40:25
User entered 'No (N)'	System	11 Dec 2020 21:40:25



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Have you been exposed to someone with 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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-12-11T15:40:15', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9003ab2d-e4da-42b2-a9bd-9d01329956dd'	System	11 Dec 2020 21:40:25
User entered 'No (N)'	System	11 Dec 2020 21:40:25

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-12-11T15:40:22', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9003ab2d-e4da-42b2-a9bd-9d01329956dd' User entered '11 Dec 2020 15:40:22'	System	11 Dec 2020 21:40:25
	System	11 Dec 2020 21:40:25

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-12-16T07:50:05', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a2b5daa9-4b36-4681-b183-90ee1704f523'	System	16 Dec 2020 13:50:48
User entered 'No (N)'	System	16 Dec 2020 13:50:48

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

Have you been exposed to someone with 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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-12-16T07:50:32', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a2b5daa9-4b36-4681-b183-90ee1704f523'	System	16 Dec 2020 13:50:48
User entered 'No (N)'	System	16 Dec 2020 13:50:48

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-12-16T07:50:42', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a2b5daa9-4b36-4681-b183-90ee1704f523' User entered '16 Dec 2020 07:50:42'	System	16 Dec 2020 13:50:48
	System	16 Dec 2020 13:50:48



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-12-23T07:50:18', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '73d3e16c-f89e-47a6-a19e-6a6bad0497ec'	System	23 Dec 2020 13:50:32
User entered 'No (N)'	System	23 Dec 2020 13:50:32

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Have you been exposed to someone with 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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-12-23T07:50:23', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '73d3e16c-f89e-47a6-a19e-6a6bad0497ec'	System	23 Dec 2020 13:50:32
User entered 'No (N)'	System	23 Dec 2020 13:50:32

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-12-23T07:50:29', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '73d3e16c-f89e-47a6-a19e-6a6bad0497ec' User entered '23 Dec 2020 07:50:29'	System	23 Dec 2020 13:50:32
	System	23 Dec 2020 13:50:32

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 16:59:17



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-12-30T07:09:05', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a89af73d-9c1e-4e28-aa38-49cb584c6fd4'	System	30 Dec 2020 13:09:44
User entered 'No (N)'	System	30 Dec 2020 13:09:44

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

Have you been exposed to someone with 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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-12-30T07:09:34', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a89af73d-9c1e-4e28-aa38-49cb584c6fd4'	System	30 Dec 2020 13:09:44
User entered 'No (N)'	System	30 Dec 2020 13:09:44

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-12-30T07:09:42', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a89af73d-9c1e-4e28-aa38-49cb584c6fd4' User entered '30 Dec 2020 07:09:42'	System	30 Dec 2020 13:09:44
	System	30 Dec 2020 13:09:44

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-01-06T09:06:58', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '979df1da-ea00-4a87-9b3a-0ab92f2a06f6' User entered 'No (N)'	System	06 Jan 2021 15:07:12
	System	06 Jan 2021 15:07:12



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

Have you been exposed to someone with 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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-01-06T09:07:03', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '979df1da-ea00-4a87-9b3a-0ab92f2a06f6'	System	06 Jan 2021 15:07:12
User entered 'No (N)'	System	06 Jan 2021 15:07:12

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-01-06T09:07:10', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '979df1da-ea00-4a87-9b3a-0ab92f2a06f6' User entered '06 Jan 2021 09:07:10'	System	06 Jan 2021 15:07:12
	System	06 Jan 2021 15:07:12

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-01-13T07:20:03', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'eef3b8c7-bfc4-4e25-84e5-1f69adca5e13'	System	13 Jan 2021 13:20:16
User entered 'No (N)'	System	13 Jan 2021 13:20:16

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Have you been exposed to someone with 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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-01-13T07:20:05', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'eef3b8c7-bfc4-4e25-84e5-1f69adca5e13'	System	13 Jan 2021 13:20:16
User entered 'No (N)'	System	13 Jan 2021 13:20:16

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-01-13T07:20:12', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'eef3b8c7-bfc4-4e25-84e5-1f69adca5e13' User entered '13 Jan 2021 07:20:12'	System	13 Jan 2021 13:20:16
	System	13 Jan 2021 13:20:16



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-01-20T08:11:22', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '5f80735d-dde7-4837-a420-39386904afe1' User entered 'No (N)'	System	20 Jan 2021 14:11:32
	System	20 Jan 2021 14:11:32

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Have you been exposed to someone with 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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-01-20T08:11:24', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '5f80735d-dde7-4837-a420-39386904afe1' User entered 'No (N)'	System	20 Jan 2021 14:11:32

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-01-20T08:11:29', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '5f80735d-dde7-4837-a420-39386904afe1' User entered '20 Jan 2021 08:11:29'	System	20 Jan 2021 14:11:32
	System	20 Jan 2021 14:11:32

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 16:59:17



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-01-27T08:09:39', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'bcd1d7ec-78f2-44f8-b5ac-c4e28ac54cdc' User entered 'No (N)'	System	27 Jan 2021 14:09:49

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Have you been exposed to someone with 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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-01-27T08:09:42', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'bcd1d7ec-78f2-44f8-b5ac-c4e28ac54cdc' User entered 'No (N)'	System	27 Jan 2021 14:09:49

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-01-27T08:09:45', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'bcd1d7ec-78f2-44f8-b5ac-c4e28ac54cdc' User entered '27 Jan 2021 08:09:45'	System	27 Jan 2021 14:09:49

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-02-03T05:45:58', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '5d4e1423-b4a9-473c-88bb-5a7db4c8c24a'	System	03 Feb 2021 11:46:07
User entered 'No (N)'	System	03 Feb 2021 11:46:07



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Have you been exposed to someone with 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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-02-03T05:46:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '5d4e1423-b4a9-473c-88bb-5a7db4c8c24a'	System	03 Feb 2021 11:46:07
User entered 'No (N)'	System	03 Feb 2021 11:46:07

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-02-03T05:46:04', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '5d4e1423-b4a9-473c-88bb-5a7db4c8c24a' User entered '03 Feb 2021 05:46:04'	System	03 Feb 2021 11:46:07
	System	03 Feb 2021 11:46:07

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-02-10T07:59:40', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '7e18ec60-dba9-45fd-93cd-24cf622668a4' User entered 'No (N)'	System	10 Feb 2021 13:59:57
	System	10 Feb 2021 13:59:57

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Have you been exposed to someone with 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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-02-10T07:59:42', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '7e18ec60-dba9-45fd-93cd-24cf622668a4' User entered 'No (N)'	System	10 Feb 2021 13:59:57
	System	10 Feb 2021 13:59:57

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-02-10T07:59:51', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '7e18ec60-dba9-45fd-93cd-24cf622668a4' User entered '10 Feb 2021 07:59:51'	System	10 Feb 2021 13:59:57
	System	10 Feb 2021 13:59:57



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-02-17T05:55:06', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '684881f9-6811-45b6-8fdf-8588be8eaae5'	System	17 Feb 2021 11:55:15
User entered 'No (N)'	System	17 Feb 2021 11:55:15

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Have you been exposed to someone with 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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-02-17T05:55:08', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '684881f9-6811-45b6-8fdf-8588be8eaae5'	System	17 Feb 2021 11:55:15
User entered 'No (N)'	System	17 Feb 2021 11:55:15

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-02-17T05:55:13', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '684881f9-6811-45b6-8fdf-8588be8eaae5' User entered '17 Feb 2021 05:55:13'	System	17 Feb 2021 11:55:15
	System	17 Feb 2021 11:55:15

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 16:59:17



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-02-24T08:16:44-06:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'adcc09ae-6d0b-4b0b-a8f2-59bbb62365b4' User entered 'No (N)'	System	24 Feb 2021 14:17:06
	System	24 Feb 2021 14:17:06

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Have you been exposed to someone with 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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-02-24T08:16:48-06:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'adcc09ae-6d0b-4b0b-a8f2-59bbb62365b4' User entered 'No (N)'	System	24 Feb 2021 14:17:06
	System	24 Feb 2021 14:17:06

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-02-24T08:16:56-06:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'adcc09ae-6d0b-4b0b-a8f2-59bbb62365b4' User entered '24 Feb 2021 14:16:56'	System	24 Feb 2021 14:17:06
	System	24 Feb 2021 14:17:06

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-03-03T09:08:21-06:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '52bbe85c-431e-4d49-ac30-a74c91c5b878'	System	03 Mar 2021 15:08:33
User entered 'No (N)'	System	03 Mar 2021 15:08:33



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

Have you been exposed to someone with 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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-03-03T09:08:26-06:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '52bbe85c-431e-4d49-ac30-a74c91c5b878'	System	03 Mar 2021 15:08:33
User entered 'No (N)'	System	03 Mar 2021 15:08:33

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-03-03T09:08:29-06:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '52bbe85c-431e-4d49-ac30-a74c91c5b878'	System	03 Mar 2021 15:08:33
User entered '03 Mar 2021 09:08:29'	System	03 Mar 2021 15:08:33

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-03-10T07:32:41-06:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'f2cc542a-5aef-483c-beb4-f776489a25e5'	System	10 Mar 2021 13:33:01
User entered 'No (N)'	System	10 Mar 2021 13:33:01

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Have you been exposed to someone with 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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-03-10T07:32:46-06:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'f2cc542a-5aef-483c-beb4-f776489a25e5'	System	10 Mar 2021 13:33:01
User entered 'No (N)'	System	10 Mar 2021 13:33:01

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-03-10T07:32:55-06:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'f2cc542a-5aef-483c-beb4-f776489a25e5'	System	10 Mar 2021 13:33:01
User entered '10 Mar 2021 07:32:55'	System	10 Mar 2021 13:33:01



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-03-17T10:58:42-05:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '129b7bf6-ae4-4e2e-b420-c8776ce3195e'	System	17 Mar 2021 15:58:52
User entered 'No (N)'	System	17 Mar 2021 15:58:52

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Have you been exposed to someone with 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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-03-17T10:58:46-05:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '129b7bf6-ae4-4e2e-b420-c8776ce3195e'	System	17 Mar 2021 15:58:52
User entered 'No (N)'	System	17 Mar 2021 15:58:52

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-03-17T10:58:50-05:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '129b7bf6-ae4-4e2e-b420-c8776ce3195e' User entered '17 Mar 2021 10:58:50'	System	17 Mar 2021 15:58:52
	System	17 Mar 2021 15:58:52

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 16:59:17



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-03-24T06:18:36-05:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '4dba8fce-f34f-4b06-99b9-421d3fb77381'	System	24 Mar 2021 11:18:47
User entered 'No (N)'	System	24 Mar 2021 11:18:47

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Have you been exposed to someone with 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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-03-24T06:18:40-05:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '4dba8fce-f34f-4b06-99b9-421d3fb77381'	System	24 Mar 2021 11:18:47
User entered 'No (N)'	System	24 Mar 2021 11:18:47

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-03-24T06:18:45-05:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '4dba8fce-f34f-4b06-99b9-421d3fb77381' User entered '24 Mar 2021 06:18:45'	System	24 Mar 2021 11:18:47
	System	24 Mar 2021 11:18:47

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-03-31T08:56:31-05:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'baaf2fb4-4dfe-495f-9366-b6eedac78134'	System	03 Apr 2021 14:56:55
User entered 'No (N)'	System	03 Apr 2021 14:56:55



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

Have you been exposed to someone with 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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-03-31T08:56:34-05:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'baaf2fb4-4dfe-495f-9366-b6eedac78134'	System	03 Apr 2021 14:56:55
User entered 'No (N)'	System	03 Apr 2021 14:56:55

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-03-31T08:56:39-05:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'baaf2fb4-4dfe-495f-9366-b6eedac78134'	System	03 Apr 2021 14:56:55
User entered '31 Mar 2021 08:56:39'	System	03 Apr 2021 14:56:55

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-04-08T19:13:39-05:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a4aa809f-09c4-46ff-b13f-6163a925957b' User entered 'No (N)'	System	09 Apr 2021 00:13:49

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Have you been exposed to someone with 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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-04-08T19:13:41-05:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a4aa809f-09c4-46ff-b13f-6163a925957b'	System	09 Apr 2021 00:13:49
User entered 'No (N)'	System	09 Apr 2021 00:13:49

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-04-08T19:13:47-05:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a4aa809f-09c4-46ff-b13f-6163a925957b' User entered '08 Apr 2021 19:13:47'	System	09 Apr 2021 00:13:49
	System	09 Apr 2021 00:13:49



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-04-14T07:45:59-05:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '3dc456e9-449b-4ba1-95b8-0d32dab108c2'	System	14 Apr 2021 15:13:40
User entered 'No (N)'	System	14 Apr 2021 15:13:40

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

Have you been exposed to someone with 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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-04-14T07:46:02-05:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '3dc456e9-449b-4ba1-95b8-0d32dab108c2'	System	14 Apr 2021 15:13:40
User entered 'No (N)'	System	14 Apr 2021 15:13:40

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-04-14T07:46:06-05:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '3dc456e9-449b-4ba1-95b8-0d32dab108c2'	System	14 Apr 2021 15:13:40
User entered '14 Apr 2021 07:46:06'	System	14 Apr 2021 15:13:40

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 16:59:17



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-04-21T16:27:25-05:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'f215e425-146c-40da-9588-688fc8bc462d' User entered 'No (N)'	System	21 Apr 2021 21:27:39
	System	21 Apr 2021 21:27:39

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Have you been exposed to someone with 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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-04-21T16:27:32-05:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'f215e425-146c-40da-9588-688fc8bc462d' User entered 'No (N)'	System	21 Apr 2021 21:27:39
	System	21 Apr 2021 21:27:39

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-04-21T16:27:35-05:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'f215e425-146c-40da-9588-688fc8bc462d' User entered '21 Apr 2021 16:27:35'	System	21 Apr 2021 21:27:39
	System	21 Apr 2021 21:27:39

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-04-28T07:06:25-05:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '6d6c9ea3-1ad5-45fc-90b1-4e288ac69c37'	System	28 Apr 2021 23:18:21
User entered 'No (N)'	System	28 Apr 2021 23:18:21



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Have you been exposed to someone with 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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-04-28T07:06:28-05:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '6d6c9ea3-1ad5-45fc-90b1-4e288ac69c37'	System	28 Apr 2021 23:18:21
User entered 'No (N)'	System	28 Apr 2021 23:18:21

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-04-28T07:06:35-05:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '6d6c9ea3-1ad5-45fc-90b1-4e288ac69c37'	System	28 Apr 2021 23:18:21
User entered '28 Apr 2021 07:06:35'	System	28 Apr 2021 23:18:21

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 16:59:17



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 16:59:17



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 16:59:17



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 16:59:17



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 16:59:17



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 16:59:17



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 16:59:17



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 16:59:17



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 16:59:17



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 16:59:17



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 16:59:17



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 16:59:17



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 16:59:17



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 16:59:17



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 16:59:17



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 16:59:17



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 16:59:17



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 16:59:17



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 16:59:17



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 16:59:17



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 16:59:17



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 16:59:17



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 16:59:17



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 16:59:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 16:59:17



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 16:59:17



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 16:59:17



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 16:59:17



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 16:59:17



**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 16:59:17

**US3812098**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:12**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 16:59:17



US3812098

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:56:12

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)	25 Apr 2021 17:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-03-03T09:08:40-06:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '0387e8cf-f5ad-4d17-a4f8-7f2854dac5d0'	System	03 Mar 2021 15:08:51
User entered 'No (N)'	System	03 Mar 2021 15:08:51

**US3812098**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:56:12**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2021-03-03T09:08:47-06:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '0387e8cf-f5ad-4d17-a4f8-7f2854dac5d0' User entered '03 Mar 2021 09:08:47'	System	03 Mar 2021 15:08:51
	System	03 Mar 2021 15:08:51

**US3812098**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:56:12**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Karen Knapp (b) (4)	05 Nov 2020 15:48:40

US3812098

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '05 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	10 Nov 2020 17:47:38
User entered '5 Nov 2020'	(b) (4)	
	Karen Knapp (b) (4)	05 Nov 2020 15:48:40
	(b) (4)	

US3812098

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	05 Nov 2020 15:48:40

US3812098

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:12

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered empty.	Karen Knapp (b) (4)	05 Nov 2020 15:48:40

US3812098

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Karen Knapp (b) (4)	05 Nov 2020 15:48:44

**US3812098**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:56:12**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:44:20
User entered 'I'	System	05 Nov 2020 15:48:44



**US3812098**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:56:12**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:56
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Karen Knapp (b) (4)	08 Dec 2020 20:56:18

**US3812098**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:56
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '8 Dec 2020'	Karen Knapp (b) (4)	08 Dec 2020 20:56:18

**US3812098**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:56:12**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:56
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	08 Dec 2020 20:56:18

US3812098

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:12

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:56
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered empty.	Karen Knapp (b) (4)	08 Dec 2020 20:56:18

US3812098

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:56
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Karen Knapp (b) (4)	08 Dec 2020 20:56:24

**US3812098**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:56:12**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:56
User entered 'I'	System	08 Dec 2020 20:56:24

US3812098

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:07:03
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 08JAN2021 for the Participant Decision Visit, however, there is no data recorded for the Participant Decision Visit. Please clarify and update as appropriate. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Larkin Wadsworth (b) (4)	23 Feb 2021 12:26:44 20 Feb 2021 19:41:45
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 08JAN2021 for the Participant Decision Visit, however, there is no data recorded for the Participant Decision Visit. Please clarify and update as appropriate. ' answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4) (b) (4)	10 Feb 2021 18:06:39
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 08JAN2021 for the Participant Decision Visit, however, there is no data recorded for the Participant Decision Visit. Please clarify and update as appropriate. ' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6) Breanna Galibert (b) (4) (b) (4)	29 Jan 2021 20:29:51 07 Jan 2021 17:56:24

**US3812098**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:07:03
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '05 Jan 2021'	Breanna Galibert (b) (4)	07 Jan 2021 17:56:24



US3812098

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:07:03
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Contact Made (CONTACT MADE)'	Breanna Galibert (b) (4)	07 Jan 2021 17:56:24

US3812098

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:12

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:07:03
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered empty.	Breanna Galibert (b) (4)	07 Jan 2021 17:56:24

US3812098

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:07:03
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 17:56:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Jan 2021 17:56:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Breanna Galibert (b) (4)	07 Jan 2021 17:56:34
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 17:56:30
User entered empty.	Breanna Galibert (b) (4)	07 Jan 2021 17:56:30

**US3812098**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:56:12**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:07:03
User entered '1'	System	07 Jan 2021 17:56:34
User entered empty.	System	07 Jan 2021 17:56:30

**US3812098**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:56:12**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:03:43
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:57
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	05 Mar 2021 22:33:01

**US3812098**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:03:43
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:57
User entered '08 Feb 2021'	Breanna Galibert (b) (4)	05 Mar 2021 22:33:01

**US3812098**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:56:12**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:03:43
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:57
User entered 'Contact Made (CONTACT MADE)'	Breanna Galibert (b) (4)	05 Mar 2021 22:33:01

US3812098

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:12

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:03:43
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:57
User entered empty.	Breanna Galibert (b) (4)	05 Mar 2021 22:33:01



US3812098

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:03:43
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:57
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	05 Mar 2021 22:33:04

**US3812098**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:56:12**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:03:43
User entered 'I'	System	05 Mar 2021 22:33:04

US3812098

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:57
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	05 Mar 2021 22:33:12

**US3812098**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:57
User entered '04 Mar 2021'	Breanna Galibert (b) (4)	05 Mar 2021 22:33:12

US3812098

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:57
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	05 Mar 2021 22:33:12

**US3812098**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:56:12**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered 'VISIT4'	System	05 Mar 2021 22:33:12

US3812098

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
User entered 'Yes (Y)'	Lyly Dang (b) (4)	02 Apr 2021 19:31:25

US3812098

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
User entered '04 Mar 2021'	Lyly Dang (b) (4)	02 Apr 2021 19:31:25



US3812098

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
User entered '11:40'	Lyly Dang (b) (4)	02 Apr 2021 19:31:25

US3812098

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered '04 Mar 2021 11:40'	System	02 Apr 2021 19:31:25

US3812098

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
User entered '97.9' F	Lyly Dang (b) (4)	02 Apr 2021 19:31:25

US3812098

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
User entered 'Oral (Oral)'	Lyly Dang (b) (4)	02 Apr 2021 19:31:25

**US3812098**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:56:12**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
User entered empty.	Lyly Dang (b) (4)	02 Apr 2021 19:31:25

US3812098

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
User entered '64'	Lyly Dang (b) (4)	02 Apr 2021 19:31:25

US3812098

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered 'bpm'	System	02 Apr 2021 19:31:25

US3812098

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
User entered '14'	Lyly Dang (b) (4)	02 Apr 2021 19:31:25



US3812098

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered 'breaths/min'	System	02 Apr 2021 19:31:25

US3812098

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
User entered '136'	Lyly Dang (b) (4)	02 Apr 2021 19:31:25

**US3812098**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:56:12**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered 'mmHg'	System	02 Apr 2021 19:31:25

US3812098

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
User entered '88'	Lyly Dang (b) (4)	02 Apr 2021 19:31:25

US3812098

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered 'mmHg'	System	02 Apr 2021 19:31:25

US3812098

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:12

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 09:09:59

US3812098

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:12

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 09:09:59

US3812098

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:56:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:57
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	05 Mar 2021 22:33:23



US3812098

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:56:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:57
User entered '04 Mar 2021'	Breanna Galibert (b) (4)	05 Mar 2021 22:33:23

US3812098

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:57
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	05 Mar 2021 22:33:29

US3812098

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:57
User entered '04 Mar 2021'	Breanna Galibert (b) (4)	05 Mar 2021 22:33:29

US3812098

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:57
User entered '12:00'	Breanna Galibert (b) (4)	05 Mar 2021 22:33:29

**US3812098**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:56:12**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered '04 Mar 2021 12:00'	System	05 Mar 2021 22:33:29

US3812098

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:57
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	05 Mar 2021 22:33:31

**US3812098**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:56:12**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:09:59
User entered 'I'	System	05 Mar 2021 22:33:31

**US3812098**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:56:12**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:59:18
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
User entered 'Yes (Y)'	Maureen Dempsey (b) (4)	05 Apr 2021 18:55:22



**US3812098**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:59:18
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
User entered '5 Apr 2021'	Maureen Dempsey (b) (4)	05 Apr 2021 18:55:22

US3812098

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:59:18
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
User entered 'Contact Made (CONTACT MADE)'	Maureen Dempsey (b) (4)	05 Apr 2021 18:55:22

US3812098

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:12

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:59:18
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
User entered empty.	Maureen Dempsey (b) (4)	05 Apr 2021 18:55:22

US3812098

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:59:18
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
User entered 'Yes (Y)'	Maureen Dempsey (b) (4)	05 Apr 2021 18:55:29

**US3812098**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:56:12**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:59:18
User entered 'I'	System	05 Apr 2021 18:55:29

US3812098

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Query 'Data is required. Please complete.' answered with 'visit has not occurred' (Site from System).	Angie Kean (b) (4)	03 May 2021 21:17:39
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	03 May 2021 19:58:40
	Angie Kean (b) (4)	03 May 2021 19:58:40
	(b) (4)	
User entered 'Yes (Y)'	Angie Kean (b) (4)	03 May 2021 19:58:06
	(b) (4)	

US3812098

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 269 'Date of Contact or Contact Attempt' is less than 237 days or greater than 243 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	03 May 2021 19:58:40
Query 'Safety Call Day 269 'Date of Contact or Contact Attempt' is less than 237 days or greater than 243 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	03 May 2021 19:58:40
User entered empty; reason for change Data Entry Error	Angie Kean (b) (4)	03 May 2021 19:58:40
User entered '03 May 2021' reason for change: Data Entry Error	Angie Kean (b) (4)	03 May 2021 19:58:21
User opened query 'Safety Call Day 269 'Date of Contact or Contact Attempt' is less than 237 days or greater than 243 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	03 May 2021 19:58:06
User entered '30 Apr 2021'	Angie Kean (b) (4)	03 May 2021 19:58:06

**US3812098**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:56:12**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Angie Kean (b) (4)	03 May 2021 19:58:40
User entered 'Contact Made (CONTACT MADE)'	Angie Kean (b) (4)	03 May 2021 19:58:06



**US3812098**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:56:12**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Angie Kean (b) (4) (b) (4)	03 May 2021 19:58:06

US3812098

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:56:12

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'No (N)'	Karen Knapp (b) (4)	30 Oct 2020 21:24:13

US3812098

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

Form: Visit Date

Generated On: 10 Jun 2021 09:56:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	03 Feb 2021 19:58:57

US3812098

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

Form: Visit Date

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '08 Jan 2021'	Breanna Galibert (b) (4)	03 Feb 2021 19:58:57

US3812098

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

Form: Visit Date

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	03 Feb 2021 19:58:57

US3812098

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

Form: Visit Date

Generated On: 10 Jun 2021 09:56:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:47
User entered 'UNBLND_DECIDE'	System	03 Feb 2021 19:58:57

US3812098

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

Form: Unblinding

Generated On: 10 Jun 2021 09:56:12

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '08 Jan 2021'	Breanna Galibert (b) (4)	03 Feb 2021 19:59:12

US3812098

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

Form: Unblinding

Generated On: 10 Jun 2021 09:56:12

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:47
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:57
User entered '0'	Breanna Galibert (b) (4)	09 Mar 2021 16:13:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:28:46



US3812098

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

Form: Unblinding

Generated On: 10 Jun 2021 09:56:12

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	03 Feb 2021 19:59:12

**US3812098**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:56:12**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:47
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:57
User entered 'Amendment 6 or later (Amendment 6 or later)'	Breanna Galibert (b) (4)	09 Mar 2021 16:13:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:28:46

US3812098

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

Form: Unblinding

Generated On: 10 Jun 2021 09:56:12

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '08 Jan 2021'	Breanna Galibert (b) (4)	03 Feb 2021 19:59:12

US3812098

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

Form: Unblinding

Generated On: 10 Jun 2021 09:56:12

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'mRNA-1273 (mRNA-1273)'	Breanna Galibert (b) (4)	03 Feb 2021 19:59:12

US3812098

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

Form: Unblinding

Generated On: 10 Jun 2021 09:56:12

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'mRNA-1273 (mRNA-1273)'	Breanna Galibert (b) (4)	03 Feb 2021 19:59:12

US3812098

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

Form: Unblinding

Generated On: 10 Jun 2021 09:56:12

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'mRNA-1273 (mRNA-1273)'	Breanna Galibert (b) (4)	03 Feb 2021 19:59:12

US3812098

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

Form: Unblinding

Generated On: 10 Jun 2021 09:56:12

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Feb 2021 19:59:12

US3812098

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

Form: Unblinding

Generated On: 10 Jun 2021 09:56:12

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:47
User entered empty.	System	03 Feb 2021 19:59:12



**US3812098**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:56:12**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:47
User entered empty.	System	03 Feb 2021 19:59:12

US3812098

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	03 Feb 2021 19:59:28

US3812098

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '08 Jan 2021'	Breanna Galibert (b) (4)	03 Feb 2021 19:59:28

US3812098

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '12:00'	Breanna Galibert (b) (4)	03 Feb 2021 19:59:28

**US3812098**

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

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:56:12**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:47
User entered '08 Jan 2021 12:00'	System	03 Feb 2021 19:59:28

US3812098

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:56:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	03 Feb 2021 19:59:35

US3812098

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:56:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '08 Jan 2021'	Breanna Galibert (b) (4)	03 Feb 2021 19:59:35

US3812098

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:56:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '12:05'	Breanna Galibert (b) (4)	03 Feb 2021 19:59:35



**US3812098**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:56:12**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:47
User entered '08 Jan 2021 12:05'	System	03 Feb 2021 19:59:35

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 10 Jun 2021 09:56:12**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:01:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:46
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	15 Sep 2020 03:41:15
User entered 'No (N)'	Karen Knapp (b) (4)	03 Sep 2020 14:21:51

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:56:12**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:24:38
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:41
User entered 'USA-US111-2020-mRNA-1273-P301000005'	System	15 Oct 2020 12:46:37
User entered 'New'	(b) (4), (b) (6)	15 Oct 2020 12:46:37

US3812098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:56:12

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:37:40
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 18:26:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 18:26:36
Data point term sent to Coder	System	14 Oct 2020 18:26:12
Coding entries removed.	(b) (4), (b) (6)	14 Oct 2020 18:25:43
User entered 'Prostate Cancer' reason for change: New Information	(b) (4), (b) (6)	14 Oct 2020 18:25:43
User coded data point as SOC: Investigations, HLGT: Cytogenetic investigations, HLT: Cell marker analyses, PT: Prostatic specific antigen increased, LLT: PSA increased - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 03:44:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 03:44:33
Data point term sent to Coder	System	15 Sep 2020 03:43:40
User entered 'ELEVATED PSA'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:56:12**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:37:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:56:12**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:37:44
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:56:12**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:37:46
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

US3812098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:56:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:37:48
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	16 Sep 2020 23:49:37
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	15 Sep 2020 03:42:54
User entered '28 Aug 2020'	(b) (4), (b) (6)	15 Sep 2020 03:42:54



**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:56:12**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 03:42:54

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:56:12**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 03:42:54

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:56:12**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:37:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

US3812098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:56:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition), then the SAE is considered resolved with sequelae and an end date should be associated at that time.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 15:09:12
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition), then the SAE is considered resolved with sequelae and an end date should be associated at that time.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 14:28:25
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition), then the SAE is considered resolved with sequelae and an end date should be associated at that time.' answered with 'End date not available at this time. Will update once resolved.' (Site from Safety).	Lyly Dang (b) (4)	13 Nov 2020 19:56:31
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:24:51
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition), then the SAE is considered resolved with sequelae and an end date should be associated at that time.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 14:25:00
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)	30 Oct 2020 12:10:46
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 'SUBJECT STILL HAS ACTIVE CANCER, AE HAS NO END DATE.' (Site from Safety).	Heather Cherniawski (b) (4)	28 Oct 2020 16:15:10
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 17:40:08

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If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 03:42:54

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:56:12**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:24:56
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 03:42:54

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:56:12**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 03:42:54

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:56:12**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:37:53
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: New Information	(b) (4), (b) (6)	14 Oct 2020 18:25:43
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	15 Sep 2020 03:42:54



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Folder: Adverse Events

Form: Adverse Events (1)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:37:56
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	14 Oct 2020 18:25:43
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:56:12**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:56:12

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:17:17
User closed query 'PV Query: The event seriousness criteria was reclassified from life-threatening to medically significant. However, the EDC was not updated. Please clarify and if necessary update the EDC.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 20:26:36
Query 'PV Query: The event seriousness criteria was reclassified from life-threatening to medically significant. However, the EDC was not updated. Please clarify and if necessary update the EDC.' answered with 'updated' (Site from Safety).	Lyly Dang (b) (4)	05 Nov 2020 22:20:51
DataPoint Un-verified.	Lyly Dang (b) (4)	05 Nov 2020 22:20:40
User entered '0' reason for change: New Information	Lyly Dang (b) (4)	05 Nov 2020 22:20:40
User opened query 'PV Query: The event seriousness criteria was reclassified from life-threatening to medically significant. However, the EDC was not updated. Please clarify and if necessary update the EDC.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 13:22:20
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:38:01
User entered '1' reason for change: New Information	(b) (4), (b) (6)	14 Oct 2020 18:25:43
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:56:12**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 03:42:54

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:56:12**

**Hospital Discharge Date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 03:42:54

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 03:42:54

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 03:42:54



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**Folder: Adverse Events**

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

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**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)	05 Nov 2020 20:31:56
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

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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)	16 Nov 2020 03:17:22
User closed query 'Per source other medically important event is checked and not life threatening per source. Please confirm with source and update accordingly. ?	(b) (4), (b) (6)	16 Nov 2020 03:17:21

Cancel

' (Site from CRA).

Query 'Per source other medically important event is checked and not life threatening per source. Please confirm with source and update accordingly. ?	Lyly Dang (b) (4)	05 Nov 2020 22:20:56
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Cancel

' answered with 'updated' (Site from CRA).

DataPoint Un-verified.	Lyly Dang (b) (4)	05 Nov 2020 22:20:40
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User entered '1' reason for change: Data Entry Error	Lyly Dang (b) (4)	05 Nov 2020 22:20:40
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DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
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User opened query 'Per source other medically important event is checked and not life threatening per source. Please confirm with source and update accordingly. ?	(b) (4), (b) (6)	05 Nov 2020 20:29:12
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Cancel

' (Site from CRA).

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[Other medically important event](#)

Audit	User	Time (GMT)
Query 'Per source other medically important event is checked. Please update life threatening per source. Please confirm with source and update accordingly.' canceled (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 20:28:30
User opened query 'Per source other medically important event is checked. Please update life threatening per source. Please confirm with source and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 20:28:06
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

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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)	05 Nov 2020 20:25:50
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:25:52
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

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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)	05 Nov 2020 20:25:48
User entered 'None (NONE)'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

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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)	05 Nov 2020 20:31:56
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 03:42:54



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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm indications for all treatment medications and chemotherapy (Indication: prostate cancer and/or multiple myeloma.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 14:25:12
Query 'PV Query: Please confirm indications for all treatment medications and chemotherapy (Indication: prostate cancer and/or multiple myeloma.' answered with 'Okay' (Site from Safety).	Angie Kean (b) (4) (b) (4)	07 Apr 2021 16:36:46
User opened query 'PV Query: Please confirm indications for all treatment medications and chemotherapy (Indication: prostate cancer and/or multiple myeloma.' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 14:24:54
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 14:58:29
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'conmed ceftriaxone indication updated to match AE term' (Site from DM).	Anya Penly (b) (4) (b) (4)	12 Nov 2020 21:13:29
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 03:59:03
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '1' reason for change: Data Entry Error	Breanna Galibert (b) (4) (b) (4)	09 Oct 2020 17:47:17
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR-RQ: Site's response noted that there was not therapeutic procedure done at this time. However, Concomitant Procedure is still selected as Other Action Taken for this AE. Please note, Concomitant Procedure should be selected if there is a therapeutic procedure performed for this AE. Please review and update as appropriate. Otherwise, provide further clarification.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 19:37:48
Query 'Per DM CLR-RQ: Site's response noted that there was not therapeutic procedure done at this time. However, Concomitant Procedure is still selected as Other Action Taken for this AE. Please note, Concomitant Procedure should be selected if there is a therapeutic procedure performed for this AE. Please review and update as appropriate. Otherwise, provide further clarification.' answered with 'BIOPSY PERFORMED' (Site from DM).	Breanna Galibert (b) (4)	28 Dec 2020 17:46:04
User opened query 'Per DM CLR-RQ: Site's response noted that there was not therapeutic procedure done at this time. However, Concomitant Procedure is still selected as Other Action Taken for this AE. Please note, Concomitant Procedure should be selected if there is a therapeutic procedure performed for this AE. Please review and update as appropriate. Otherwise, provide further clarification.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 03:14:26
User closed query 'Per DM CLR: RQ: Response noted, however, the procedure recorded in the Con Proc eCRF for this AE is diagnostic. Review if there is a therapeutic procedure done and record as appropriate. Otherwise, update the response.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 15:50:36
Query 'Per DM CLR: RQ: Response noted, however, the procedure recorded in the Con Proc eCRF for this AE is diagnostic. Review if there is a therapeutic procedure done and record as appropriate. Otherwise, update the response.' answered with 'no therapeutic procedure done at this time. ' (Site from DM).	Any Penly (b) (4)	12 Nov 2020 21:25:41

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: RQ: Response noted, however, the procedure recorded in the Con Proc eCRF for this AE is diagnostic. Review if there is a therapeutic procedure done and record as appropriate. Otherwise, update the response.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 03:57:39
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
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.'	(b) (4), (b) (6)	23 Oct 2020 16:43:49
(Site from DM).		
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.'	Anya Penly (b) (4)	21 Oct 2020 14:41:35
' answered with 'BIOPSY OF PROSTATE on 02 OCT 2020 is recorded in con procedures' (Site from DM).	(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 Oct 2020 06:01:07
(Site from DM).		
User entered 'I'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 14:25:15
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 12:10:50
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Subject not resolved. Expecting resolution before the end of the trial per Sub I Clement NPC' (Site from Safety).	Heather Cherniawski (b) (4)	28 Oct 2020 16:20:01
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 17:40:18
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

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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)	05 Nov 2020 20:31:56
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 03:42:54

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:05
DataPoint Un-verified.	Lyly Dang (b) (4)	15 Feb 2021 01:50:29

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:56:12

[Narrative](#)

Audit	User	Time (GMT)
User entered 'This is a 67-year-old male with a history of vasectomy, right inguinal hernia with repair, daily alcohol use, anxiety, Vitamin B12 deficiency, thyroid nodules, and microalbuminuria. He was initially diagnosed with stage T1c prostate cancer in October 2020 after a rising PSA. His prostate biopsy showed Gleason score 7- adenocarcinoma and his most recent PSA was 7.4 in December 2020. He completed a CT PET on 17NOV2020 due to complaints of lumbar pain. The final report showed widespread marrow activity of lytic lesions throughout the axial and appendicular skeleton. The subject was diagnosed with multiple myeloma on 24NOV2020. Subject completed a peripheral blood smear and a bone marrow aspirate and biopsy on 02DEC2020. Subject was conclusive for macrocytic anemia and plasma cell myeloma. Subject was given Tramadol 100mg q 6 hours PRN for pain control. Lupron 25 mg daily was started for his prostate cancer on 04DEC2020. His recommended chemotherapy included Velcade SQ weekly, Revlimid 25mg PO daily days 1-14 every 21 days, and dexamethasone 20mg PO day of and day after Velcade injection prescribed on 08DEC2020. Velcade dose is not specified in medical records. Aspirin 81mg daily, Compazine 10mg q 6 hours PRN, and Pepcid 20mg daily also prescribed on 08DEC2020. Monthly Xgeva 120mg SQ was also started 08DEC2020. Radiation is also being considered for prostate cancer, rather than prostatectomy, due to treatment for multiple myeloma. During 22DEC2020 visit, he was started on Lidoderm 5% patch to affected area daily for additional pain control. He was also started on Lexapro 10mg daily during this visit for worsening anxiety. Last reported visit was 05JAN2021, which continues the established plan of care. We will continue to follow the safety and outcome of this subject.' reason for change: New Information	Lyly Dang (b) (4)	15 Feb 2021 01:50:29

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:55:50
User closed query 'PV Query: Will the subject receive any treatment for prostate cancer (i.e. radiation, surgery, etc)?' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 14:28:33
Query 'PV Query: Will the subject receive any treatment for prostate cancer (i.e. radiation, surgery, etc)?' answered with 'Subject is scheduled for a prostatectomy on 13 Jan 2021' (Site from Safety).	Lyly Dang (b) (4)	13 Nov 2020 19:55:52
User entered '14 OCT 2020 AT 10:30 AM-SUBJECT CALLED TODAY AND REPORTED ELEVATED PSA IS NOW A DIAGNOSIS OF PROSTATE CANCER. PSA LEVEL COLLECTED ON AUG 03, 2020 WAS 6.0 NG/ML. Subject is scheduled for a prostatectomy on 13 Jan 2021. Subject denies any other changes in treatment or medications at this time.' reason for change: New Information	Lyly Dang (b) (4)	13 Nov 2020 19:54:07
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query open until information is available.' canceled (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 19:06:26
User closed query 'PV Query: Please provide the subject's PSA levels prior to study enrollment and on 28 AUG 2020 (screening for prostate cancer).' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 20:26:49
Query 'PV Query: Please provide the subject's PSA levels prior to study enrollment and on 28 AUG 2020 (screening for prostate cancer).' answered with 'updated' (Site from Safety).	Lyly Dang (b) (4)	05 Nov 2020 22:21:03
DataPoint Un-verified.	Lyly Dang (b) (4)	05 Nov 2020 22:20:40



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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered '14 OCT 2020 AT 10:30 AM-SUBJECT CALLED TODAY AND REPORTED ELEVATED PSA IS NOW A DIAGNOSIS OF PROSTATE CANCER. PSA level collected on Aug 03, 2020 was 6.0 ng/mL. WILL RETRIEVE MR FOR THIS DIAGNOSIS. SUBJECT REPORTS HE HAS NOT GOTTEN A PLAN YET FOR DX AND IS GOING TO MAKE A FOLLOW UP APPOINTMENT SOON.' reason for change: New Information DataPoint Verified.	Lyly Dang (b) (4)	05 Nov 2020 22:20:40
	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 14:26:00
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). ' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 12:10:51
User opened query 'PV Query: Will the subject receive any treatment for prostate cancer (i.e. radiation, surgery, etc)? ' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 13:21:41
User opened query 'PV Query: Please provide the subject's PSA levels prior to study enrollment and on 28 AUG 2020 (screening for prostate cancer). ' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 13:21:25

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' answered with 'Subject has not yet been seen for treatment plan. Will update when given and completing one per SUB I CLEMENT NPC' (Site from Safety).	Heather Cherniawski (b) (4)	28 Oct 2020 16:21:04
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 17:40:33
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	14 Oct 2020 18:27:41
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	14 Oct 2020 18:27:41
User entered '14 OCT 2020 at 10:30 AM- Subject called today and reported elevated PSA is now a diagnosis of prostate cancer. Will retrieve MR for this diagnosis. Subject reports he has not gotten a plan yet for dx and is going to make a follow up appointment soon. Please note that subject just found out about prostate cancer dx yesterday.' reason for change: New Information	(b) (4), (b) (6)	14 Oct 2020 18:27:41
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	14 Oct 2020 18:25:43
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 03:42:54

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:56:12**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 18:25:43
User entered '0'	System	15 Sep 2020 03:42:54

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:56:12**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Sep 2020 03:42:54

US3812098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:12

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain in hip - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 19:59:53
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 19:59:53
Data point term sent to Coder	System	01 Oct 2020 19:59:07
User entered 'BILATERAL HIP PAIN'	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:58:11

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:56:12**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'No (N)'	Breanna Galibert (b) (4)	01 Oct 2020 19:58:11
	(b) (4)	

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:56:12**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'No (N)'	Breanna Galibert (b) (4)	01 Oct 2020 19:58:11
	(b) (4)	

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:56:12**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:58:11



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '24 Sep 2020'	Breanna Galibert (b) (4)	01 Oct 2020 19:58:11
	(b) (4)	

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:56:12**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:58:11

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:56:12**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 19:58:11

US3812098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:12

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 08:49:07
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' answered with 'UPDATED' (Site from DM).	Breanna Galibert (b) (4)	07 Jan 2021 17:55:12
DataPoint Un-verified.	Breanna Galibert (b) (4)	07 Jan 2021 17:55:01
User entered 'No (N)' reason for change: New Information	Breanna Galibert (b) (4)	07 Jan 2021 17:55:01
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 03:19:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	01 Oct 2020 19:58:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	Breanna Galibert (b) (4) (b) (4)	07 Jan 2021 17:55:01
User entered '11 Dec 2020' reason for change: New Information	Breanna Galibert (b) (4) (b) (4)	07 Jan 2021 17:55:01
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	05 Nov 2020 20:31:56
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:58:11

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:56:12**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Breanna Galibert (b) (4)	01 Oct 2020 19:58:11
	(b) (4)	

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:56:12**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 19:58:11

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:56:12**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'Grade 1/Mild (Grade 1/Mild)'	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:58:11



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:56:12**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'No (N)'	Breanna Galibert (b) (4)	01 Oct 2020 19:58:11
	(b) (4)	

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:56:12**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Breanna Galibert (b) (4)	01 Oct 2020 19:58:11
	(b) (4)	

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:56:12**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Breanna Galibert (b) (4)	01 Oct 2020 19:58:11
	(b) (4)	

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:56:12**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:58:11

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:56:12**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Breanna Galibert (b) (4)	01 Oct 2020 19:58:11
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:56:12**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Breanna Galibert (b) (4)	01 Oct 2020 19:58:11
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:56:12**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:58:11

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:56:12**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Breanna Galibert (b) (4)	01 Oct 2020 19:58:11
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:56:12**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Breanna Galibert (b) (4)	01 Oct 2020 19:58:11
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:56:12**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Breanna Galibert (b) (4)	01 Oct 2020 19:58:11
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Breanna Galibert (b) (4)	01 Oct 2020 19:58:11
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:56:12**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:58:11

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:56:12**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:58:11

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:56:12**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'Not Applicable (NOT APPLICABLE)'	Breanna Galibert (b) (4)	01 Oct 2020 19:58:11
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:56:12**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Breanna Galibert (b) (4)	01 Oct 2020 19:58:11
	(b) (4)	

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:56:12**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'I'	Breanna Galibert (b) (4)	01 Oct 2020 19:58:11
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:56:12**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Breanna Galibert (b) (4)	01 Oct 2020 19:58:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:12

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Breanna Galibert (b) (4)	07 Jan 2021 17:55:01
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Breanna Galibert (b) (4)	07 Jan 2021 17:55:01
New Information	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Breanna Galibert (b) (4)	01 Oct 2020 19:58:11
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:56:12**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:58:11

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:56:12**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:58:11

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:56:12**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Oct 2020 19:58:11

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:56:12**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Oct 2020 19:58:11

US3812098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:56:12

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Neck pain, LLT: Neck pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 20:01:00
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 20:01:00
Data point term sent to Coder	System	01 Oct 2020 20:00:09
User entered 'NECK PAIN'	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:59:16

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:56:12**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'No (N)'	Breanna Galibert (b) (4)	01 Oct 2020 19:59:16
	(b) (4)	



**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:56:12**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:59:16

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:56:12**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:59:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:56:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '22 Sep 2020' reason for change: Data Entry Error	Anya Penly (b) (4)	21 Oct 2020 14:35:22
User entered '24 Sep 2020'	Breanna Galibert (b) (4)	01 Oct 2020 19:59:16

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:56:12**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:59:16

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:56:12**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 19:59:16

US3812098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:56:12

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 16:35:06
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' answered with 'updated' (Site from DM).	Breanna Galibert (b) (4)	04 Jan 2021 20:32:29
DataPoint Un-verified.	Breanna Galibert (b) (4)	04 Jan 2021 20:32:23
User entered 'No (N)' reason for change: New Information	Breanna Galibert (b) (4)	04 Jan 2021 20:32:23
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 03:19:09
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	01 Oct 2020 19:59:16

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Folder: Adverse Events

Form: Adverse Events (3)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	Breanna Galibert (b) (4) (b) (4)	04 Jan 2021 20:32:23
User entered '30 Nov 2020' reason for change: New Information	Breanna Galibert (b) (4) (b) (4)	04 Jan 2021 20:32:23
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	05 Nov 2020 20:31:56
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:59:16

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Breanna Galibert (b) (4)	01 Oct 2020 19:59:16
	(b) (4)	



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**Folder: Adverse Events**

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**Generated On: 10 Jun 2021 09:56:12**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 19:59:16

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:56:12**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'Grade 1/Mild (Grade 1/Mild)'	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:59:16

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:56:12**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'No (N)'	Breanna Galibert (b) (4)	01 Oct 2020 19:59:16
	(b) (4)	

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Breanna Galibert (b) (4)	01 Oct 2020 19:59:16
	(b) (4)	

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:56:12**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Breanna Galibert (b) (4)	01 Oct 2020 19:59:16
	(b) (4)	

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:56:12**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:59:16

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:56:12**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Breanna Galibert (b) (4)	01 Oct 2020 19:59:16
	(b) (4)	

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:56:12**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Breanna Galibert (b) (4)	01 Oct 2020 19:59:16
	(b) (4)	



**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:59:16

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:56:12**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:59:16

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:56:12**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Breanna Galibert (b) (4)	01 Oct 2020 19:59:16
	(b) (4)	

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:56:12**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Breanna Galibert (b) (4)	01 Oct 2020 19:59:16
	(b) (4)	

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:56:12**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Breanna Galibert (b) (4)	01 Oct 2020 19:59:16
	(b) (4)	

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:56:12**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:59:16

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:56:12**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:59:16

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:56:12**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'Not Applicable (NOT APPLICABLE)'	Breanna Galibert (b) (4)	01 Oct 2020 19:59:16
	(b) (4)	



**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:56:12**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Breanna Galibert (b) (4)	01 Oct 2020 19:59:16
	(b) (4)	

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:56:12**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'I'	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:59:16

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:56:12**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Breanna Galibert (b) (4)	01 Oct 2020 19:59:16
	(b) (4)	

US3812098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:56:12

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Breanna Galibert (b) (4)	04 Jan 2021 20:32:23
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Breanna Galibert (b) (4)	04 Jan 2021 20:32:23
New Information	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Breanna Galibert (b) (4)	01 Oct 2020 19:59:16
	(b) (4)	

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:56:12**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:59:16

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:56:12**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:59:16

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:56:12**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Oct 2020 19:59:16

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:56:12**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Oct 2020 19:59:16



US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:12

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataract aggravated - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 14:40:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 14:40:02
Data point term sent to Coder	System	21 Oct 2020 14:35:09
User entered 'worsening left cataract'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:56:12**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'Yes (Y)'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:56:12**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'No (N)'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:56:12**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'No (N)'	Anya Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '15 Oct 2020'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:56:12**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:56:12**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 14:34:43

US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:12

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please verify if this AE is still ongoing as it was noted that Cataract Removal was already performed. Please review and update the dates if applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 16:36:10
Query 'Per DM CLR: Please verify if this AE is still ongoing as it was noted that Cataract Removal was already performed. Please review and update the dates if applicable. Otherwise, clarify.' answered with 'updated' (Site from DM).	Breanna Galibert (b) (4)	04 Jan 2021 20:29:25
DataPoint Un-verified.	Breanna Galibert (b) (4)	04 Jan 2021 20:29:20
User entered 'No (N)' reason for change: New Information	Breanna Galibert (b) (4)	04 Jan 2021 20:29:20
User opened query 'Per DM CLR: Please verify if this AE is still ongoing as it was noted that Cataract Removal was already performed. Please review and update the dates if applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 03:14:51
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'Yes (Y)'	Any Penly (b) (4)	21 Oct 2020 14:34:43



US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	Breanna Galibert (b) (4) (b) (4)	04 Jan 2021 20:29:20
User entered '15 Oct 2020' reason for change: New Information	Breanna Galibert (b) (4) (b) (4)	04 Jan 2021 20:29:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Anya Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:56:12**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:56:12**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 14:34:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:56:12**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:56:12**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'No (N)'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:56:12**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:56:12**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:56:12**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Anya Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43



US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:12

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Anya Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:12

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Anya Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:56:12**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:56:12**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Anya Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:56:12**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:56:12**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Anya Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:56:12**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:56:12**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'Not Related (NOT RELATED)'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43



**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:56:12**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'Not Related (NOT RELATED)'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:56:12**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'Not Applicable (NOT APPLICABLE)'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:56:12**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:56:12**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:56:12**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'I'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:12

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Breanna Galibert (b) (4) (b) (4)	04 Jan 2021 20:29:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Breanna Galibert (b) (4) (b) (4)	04 Jan 2021 20:29:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:56:12**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:56:12**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43



**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:56:12**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Oct 2020 14:34:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:56:12**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Oct 2020 14:34:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:56:12**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:37:13
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:36:50
User entered 'USA-US111-2020-mRNA-1273-P301000020'	System	09 Dec 2020 20:25:37
User entered 'New'	(b) (4), (b) (6)	09 Dec 2020 20:25:37

US3812098

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:56:12

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:37:13
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Plasma cell neoplasms, HLT: Plasma cell myelomas, PT: Plasma cell myeloma, LLT: Multiple myeloma - version MedDRA\\23.0.	Coder Import (b) (4)	07 Jan 2021 17:56:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	07 Jan 2021 17:56:43
Data point term sent to Coder	System	07 Jan 2021 17:56:26
Coding entries removed.	Breanna Galibert (b) (4)	07 Jan 2021 17:56:02
User entered 'MULTIPLE MYELOMA' reason for change: New Information	(b) (4)	07 Jan 2021 17:56:02
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skeletal neoplasms malignant and unspecified, HLT: Bone neoplasms malignant (excl sarcomas), PT: Bone cancer, LLT: Bone cancer - version MedDRA\\23.0.	Breanna Galibert (b) (4)	07 Jan 2021 17:56:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 01:52:50
Data point term sent to Coder	(b) (4)	09 Dec 2020 01:52:50
User entered 'Bone Cancer'	System	09 Dec 2020 01:51:19
	Lyly Dang (b) (4)	09 Dec 2020 01:50:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:56:12**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:37:13
User entered 'Yes (Y)'	Lyly Dang (b) (4)	09 Dec 2020 01:50:43

US3812098

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:56:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:37:13
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Dec 2020 01:50:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Dec 2020 01:50:49
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	09 Dec 2020 01:50:49
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Dec 2020 01:50:43
User entered empty.	Lyly Dang (b) (4)	09 Dec 2020 01:50:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:56:12**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:37:13
User entered 'No (N)'	Lyly Dang (b) (4)	09 Dec 2020 01:50:43

US3812098

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:56:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:28:10
User closed query 'Please clarify per documentation, if start date should be noted as 24Nov2020.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 19:28:08
Query 'Please clarify per documentation, if start date should be noted as 24Nov2020.' answered with 'updated' (Site from CRA).	Angie Kean (b) (4) (b) (4)	06 Apr 2021 21:46:40
User entered '24 Nov 2020' reason for change: Data Entry Error	Lyly Dang (b) (4)	06 Apr 2021 15:33:02
User opened query 'Please clarify per documentation, if start date should be noted as 24Nov2020.' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 17:39:01
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 17:38:22
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:37:13
User entered '1 Dec 2020'	Lyly Dang (b) (4)	09 Dec 2020 01:50:43



**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:56:12**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:37:13
User entered empty.	Lyly Dang (b) (4)	09 Dec 2020 01:50:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:56:12**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Dec 2020 01:50:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:56:12**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:37:13
User entered 'Yes (Y)'	Lyly Dang (b) (4)	09 Dec 2020 01:50:43

US3812098

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:56:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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). DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 22:31:36
	(b) (4), (b) (6)	16 Mar 2021 17:37:13
User entered empty.	Lyly Dang (b) (4)	09 Dec 2020 01:50:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:56:12**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:37:13
User entered empty.	Lyly Dang (b) (4)	09 Dec 2020 01:50:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:56:12**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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.' canceled (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 22:31:42
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 14:48:02
User entered empty.	System	09 Dec 2020 01:50:43

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:56:12

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:37:13
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Lyly Dang (b) (4)	09 Dec 2020 19:29:43
User entered 'Grade 4 (Grade 4)'	Lyly Dang (b) (4)	09 Dec 2020 01:50:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:56:12**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:37:13
User entered 'Yes (Y)'	Lyly Dang (b) (4)	09 Dec 2020 01:50:43



**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:56:12**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:37:13
User entered '0'	Lyly Dang (b) (4)	09 Dec 2020 01:50:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:56:12**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:37:13
User entered '0'	Lyly Dang (b) (4)	09 Dec 2020 01:50:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:56:12**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'PV Query: It was reported that the subject was admitted to the hospital for a stem cell transplant. Please consider updating the seriousness criteria to reflect this.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 11:50:56
	(b) (4), (b) (6)	16 Mar 2021 17:37:13
User entered '0'	Lyly Dang (b) (4)	09 Dec 2020 01:50:43

US3812098

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:56:12

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:37:13
User entered empty.	Lyly Dang (b) (4)	09 Dec 2020 01:50:43

US3812098

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:56:12

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:37:13
User entered empty.	Lyly Dang (b) (4)	09 Dec 2020 01:50:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:56:12**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:37:13
User entered empty.	Lyly Dang (b) (4)	09 Dec 2020 01:50:43

US3812098

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:56:12

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:37:13
User entered empty.	Lyly Dang (b) (4)	09 Dec 2020 01:50:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:56:12**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:37:13
User entered '0'	Lyly Dang (b) (4)	09 Dec 2020 01:50:43



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:56:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:37:13
User entered '0'	Lyly Dang (b) (4)	09 Dec 2020 01:50:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:56:12**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:37:13
User entered '1'	Lyly Dang (b) (4)	09 Dec 2020 01:50:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:56:12**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:37:13
User entered 'Not Related (NOT RELATED)'	Lyly Dang (b) (4)	09 Dec 2020 01:50:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:56:12**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:37:13
User entered 'Not Related (NOT RELATED)'	Lyly Dang (b) (4)	09 Dec 2020 01:50:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:56:12**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:37:13
User entered 'Not Applicable (NOT APPLICABLE)'	Lyly Dang (b) (4)	09 Dec 2020 01:50:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:56:12**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:37:13
User entered '0'	Lyly Dang (b) (4)	09 Dec 2020 01:50:43

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:56:12

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:37:13
User entered 'I'	Lyly Dang (b) (4)	09 Dec 2020 01:50:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:56:12**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:37:13
User entered '0'	Lyly Dang (b) (4)	09 Dec 2020 01:50:43



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:56:12

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:37:13
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 14:48:48
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Lyly Dang (b) (4)	09 Dec 2020 01:50:43

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:56:12**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:37:13
User entered empty.	Lyly Dang (b) (4)	09 Dec 2020 01:50:43

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:56:12

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:37:30
User closed query 'Per DM CLR: Narrative indicates that the subject had Peripheral Blood Smear, Bone Marrow Aspirate and Biopsy. However, there are no corresponding Concomitant Procedures record that match the information. Please review and update to record the procedures on the appropriate eCRF page. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 15:10:01
User closed query 'PV Query: Please confirm start date for con med Zanaflex for multiple myeloma, which is listed as 20 Nov 2020, however multiple myeloma wasn't diagnosed until 24 Nov 2020. ' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 14:08:56
Query 'PV Query: Please confirm start date for con med Zanaflex for multiple myeloma, which is listed as 20 Nov 2020, however multiple myeloma wasn't diagnosed until 24 Nov 2020. ' answered with 'subject was symptomatic for multiple myeloma prior to confirmed diagnosis which was 24 NOV 2020. Per monitor, start date was changed to reflect the date of confirming biopsy. subject was treated for symptoms prior to this date. ' (Site from Safety).	Angie Kean (b) (4) (b) (4)	07 Apr 2021 16:35:40
Query 'Per DM CLR: Narrative indicates that the subject had Peripheral Blood Smear, Bone Marrow Aspirate and Biopsy. However, there are no corresponding Concomitant Procedures record that match the information. Please review and update to record the procedures on the appropriate eCRF page. Otherwise, clarify.' answered with 'updated' (Site from DM).	Angie Kean (b) (4) (b) (4)	07 Apr 2021 16:32:57
User closed query 'PV Query: Please confirm start date for con med Norco for multiple myeloma, which is listed as 08 Nov 2020, however multiple myeloma wasn't diagnosed on 24 Nov 2020. ' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 15:21:01
User closed query 'PV Query: The subject was first diagnosed with multiple myeloma on 24 Nov 2020: However, the start date is reported as 01 Dec 2020. Please clarify on the start date. ' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 15:20:58

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:56:12

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: The subject was first diagnosed with multiple myeloma on 24 Nov 2020: However, the start date is reported as 01 Dec 2020. Please clarify on the start date. ' answered with 'start date has been updated' (Site from Safety).	Angie Kean (b) (4) (b) (4)	06 Apr 2021 21:53:00
Query 'PV Query: Please confirm start date for con med Norco for multiple myeloma, which is listed as 08 Nov 2020, however multiple myeloma wasn't diagnosed on 24 Nov 2020. ' answered with 'updated start date' (Site from Safety).	Angie Kean (b) (4) (b) (4)	06 Apr 2021 21:48:43
DataPoint Un-verified.	Lyly Dang (b) (4) (b) (4) (b) (4)	06 Apr 2021 15:37:33

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:56:12

[Narrative](#)

Audit	User	Time (GMT)
User entered "THIS IS A 67-YEAR-OLD MALE WITH A HISTORY OF VASECTOMY, RIGHT INGUINAL HERNIA WITH REPAIR, DAILY ALCOHOL USE, ANXIETY, VITAMIN B12 DEFICIENCY, THYROID NODULES, AND MICROALBUMINURIA. HE WAS INITIALLY DIAGNOSED WITH STAGE T1C PROSTATE CANCER IN OCTOBER 2020 AFTER A RISING PSA. HIS PROSTATE BIOPSY SHOWED GLEASON SCORE 7- ADENOCARCINOMA AND HIS MOST RECENT PSA WAS 7.4 IN DECEMBER 2020. HE COMPLETED A CT PET ON 17NOV2020 DUE TO COMPLAINTS OF LUMBAR PAIN. THE FINAL REPORT SHOWED WIDESPREAD MARROW ACTIVITY OF LYTIC LESIONS THROUGHOUT THE AXIAL AND APPENDICULAR SKELETON. THE SUBJECT WAS DIAGNOSED WITH MULTIPLE MYELOMA ON 24NOV2020. SUBJECT COMPLETED A PERIPHERAL BLOOD SMEAR AND A BONE MARROW ASPIRATE AND BIOPSY ON 02DEC2020. SUBJECT WAS CONCLUSIVE FOR MACROCYTIC ANEMIA AND PLASMA CELL MYELOMA. SUBJECT WAS GIVEN TRAMADOL 100MG Q 6 HOURS PRN FOR PAIN CONTROL. LUPRON 25 MG DAILY WAS STARTED FOR HIS PROSTATE CANCER ON 04DEC2020. HIS RECOMMENDED CHEMOTHERAPY INCLUDED VELCADE SQ WEEKLY, REVLIMID 25MG PO DAILY DAYS 1-14 EVERY 21 DAYS, AND DEXAMETHASONE 20MG PO DAY OF AND DAY AFTER VELCADE INJECTION PRESCRIBED ON 08DEC2020. VELCADE DOSE IS NOT SPECIFIED IN MEDICAL RECORDS. ASPIRIN 81MG DAILY, COMPAZINE 10MG Q 6 HOURS PRN, AND PEPCID 20MG DAILY ALSO PRESCRIBED ON 08DEC2020. MONTHLY XGEVA 120MG SQ WAS ALSO STARTED 08DEC2020. RADIATION IS ALSO BEING CONSIDERED FOR PROSTATE CANCER, RATHER THAN PROSTATECTOMY,	Lyly Dang (b) (4)	06 Apr 2021 15:37:33

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:56:12

[Narrative](#)

Audit	User	Time (GMT)
DUE TO TREATMENT FOR MULTIPLE MYELOMA. DURING 22DEC2020 VISIT, HE WAS STARTED ON LIDODERM 5% PATCH TO AFFECTED AREA DAILY FOR ADDITIONAL PAIN CONTROL. HE WAS ALSO STARTED ON LEXAPRO 10MG DAILY DURING THIS VISIT FOR WORSENING ANXIETY. LAST REPORTED VISIT WAS 05JAN2021, WHICH CONTINUES THE ESTABLISHED PLAN OF CARE. WE WILL CONTINUE TO FOLLOW THE SAFETY AND OUTCOME OF THIS SUBJECT. [06 Apr 2021]		
Subject was admitted on March 31st for a "stem cell transplant" to treat his multiple myeloma. This was a planned event and he is anticipated to be discharged on April 15th.' reason for change: Data Entry Error DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:37:13
User opened query 'Per DM CLR: Narrative indicates that the subject had Peripheral Blood Smear, Bone Marrow Aspirate and Biopsy. However, there are no corresponding Concomitant Procedures record that match the information. Please review and update to record the procedures on the appropriate eCRF page. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 15:42:04
User opened query 'PV Query: Please confirm start date for con med Zanaflex for multiple myeloma, which is listed as 20 Nov 2020, however multiple myeloma wasn't diagnosed until 24 Nov 2020. ' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 18:13:08
User opened query 'PV Query: Please confirm start date for con med Norco for multiple myeloma, which is listed as 08 Nov 2020, however multiple myeloma wasn't diagnosed on 24 Nov 2020. ' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 18:13:02
User opened query 'PV Query: The subject was first diagnosed with multiple myeloma on 24 Nov 2020: However, the start date is reported as 01 Dec 2020. Please clarify on the start date. ' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 18:12:28
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 18:34:16
PRODUCTION RELEASE (v12.003 EAB) (1725)		1969 of 2764

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:56:12**

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Updated' (Site from Safety).	Lyly Dang (b) (4)	08 Feb 2021 20:57:49

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:56:12

[Narrative](#)

Audit	User	Time (GMT)
User entered 'This is a 67-year-old male with a history of vasectomy, right inguinal hernia with repair, daily alcohol use, anxiety, Vitamin B12 deficiency, thyroid nodules, and microalbuminuria. He was initially diagnosed with stage T1c prostate cancer in October 2020 after a rising PSA. His prostate biopsy showed Gleason score 7-adenocarcinoma and his most recent PSA was 7.4 in December 2020. He completed a CT PET on 17NOV2020 due to complaints of lumbar pain. The final report showed widespread marrow activity of lytic lesions throughout the axial and appendicular skeleton. The subject was diagnosed with multiple myeloma on 24NOV2020. Subject completed a peripheral blood smear and a bone marrow aspirate and biopsy on 02DEC2020. Subject was conclusive for macrocytic anemia and plasma cell myeloma. Subject was given Tramadol 100mg q 6 hours PRN for pain control. Lupron 25 mg daily was started for his prostate cancer on 04DEC2020. His recommended chemotherapy included Velcade SQ weekly, Revlimid 25mg PO daily days 1-14 every 21 days, and dexamethasone 20mg PO day of and day after Velcade injection prescribed on 08DEC2020. Velcade dose is not specified in medical records. Aspirin 81mg daily, Compazine 10mg q 6 hours PRN, and Pepcid 20mg daily also prescribed on 08DEC2020. Monthly Xgeva 120mg SQ was also started 08DEC2020. Radiation is also being considered for prostate cancer, rather than prostatectomy, due to treatment for multiple myeloma. During 22DEC2020 visit, he was started on Lidoderm 5% patch to affected area daily for additional pain control. He was also started on Lexapro 10mg daily during this visit for worsening anxiety. Last reported visit was 05JAN2021, which continues the established plan of care. We will continue to follow the safety and outcome of this subject.' reason for change: Data Entry Error	Lyly Dang (b) (4)	08 Feb 2021 20:57:39



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:56:12

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 14:47:22
User entered 'During the subject's D119 safety call, subject reported that he was diagnosed with "bone cancer" and started undergoing chemotherapy on 12/08/20. Since it is currently unknown if "bone cancer" was due to possible prostate CA metastasis or due to a separate etiology, site is submitting a new SAE'	Lyly Dang (b) (4)	09 Dec 2020 01:50:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:56:12**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Dec 2020 01:50:43

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:56:12**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Dec 2020 01:50:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:56:12

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety aggravated - version MedDRA\\23.0.	Coder Import (b) (4)	03 Feb 2021 19:45:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Feb 2021 19:45:28
Data point term sent to Coder	System	03 Feb 2021 19:44:45
User entered 'worsening anxiety'	Breanna Galibert (b) (4)	03 Feb 2021 19:44:01

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:56:12**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:44:01

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:56:12**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:44:01

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:56:12**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:44:01

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:56:12

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '05 Jan 2021'	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:44:01



**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:44:01

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:56:12**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 19:44:01

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:56:12**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: New Information	Breanna Galibert (b) (4)	08 Feb 2021 21:36:54
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	03 Feb 2021 19:44:01

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:56:12**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '05 Feb 2021' reason for change: New Information	Breanna Galibert (b) (4)	08 Feb 2021 21:36:54
User entered empty.	Breanna Galibert (b) (4)	03 Feb 2021 19:44:01

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:56:12**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:44:01

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:56:12**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 19:44:01

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:56:12**

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Breanna Galibert (b) (4)	03 Feb 2021 19:44:01
	(b) (4)	

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:56:12**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:44:01



**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:56:12**

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:44:01

US3812098

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:56:12

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:44:01

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:56:12**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:44:01

US3812098

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:56:12

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:44:01

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:56:12**

**Hospital Discharge Date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:44:01

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:56:12**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:44:01

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:56:12**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:44:01

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:56:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:44:01



**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:56:12**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:44:01

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:56:12**

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:44:01

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:56:12**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:44:01

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:56:12**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:44:01

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:56:12**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:44:01

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:56:12**

[None](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:44:01

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:56:12

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'I'	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:44:01

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:56:12**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:44:01



**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:56:12**

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Breanna Galibert (b) (4)	08 Feb 2021 21:36:54
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Breanna Galibert (b) (4)	03 Feb 2021 19:44:01

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:56:12**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:44:01

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:56:12**

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:44:01

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:56:12**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Feb 2021 19:44:01

**US3812098**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:56:12**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Feb 2021 19:44:01

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:01:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:18:07
User closed query 'Per CDM Re-query: 'Was any medication taken today for pain and fever?' is recorded Yes from 10-sep-2020 to 12-sep-2020. Site response on Temperature day form, Diary Dose 2 folder (Dose Temp Log Line 2 and 3) indicates 'subject was contacted'. However, corresponding concomitant medication has not been reported under Prior/Concomitant Medication and Vaccination section of the eCRF. Please review and update. Else clarify.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 15:10:02
Query 'Per CDM Re-query: 'Was any medication taken today for pain and fever?' is recorded Yes from 10-sep-2020 to 12-sep-2020. Site response on Temperature day form, Diary Dose 2 folder (Dose Temp Log Line 2 and 3) indicates 'subject was contacted'. However, corresponding concomitant medication has not been reported under Prior/Concomitant Medication and Vaccination section of the eCRF. Please review and update. Else clarify.' answered with 'concomitant procedure added to EDC' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 18:31:26
User opened query 'Per CDM Re-query: 'Was any medication taken today for pain and fever?' is recorded Yes from 10-sep-2020 to 12-sep-2020. Site response on Temperature day form, Diary Dose 2 folder (Dose Temp Log Line 2 and 3) indicates 'subject was contacted'. However, corresponding concomitant medication has not been reported under Prior/Concomitant Medication and Vaccination section of the eCRF. Please review and update. Else clarify.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 13:26:05
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:58:51

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:56:12

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: UBIDECARENONE, PRODUCTSYNONYM: COENZYME Q10 [UBIDECARENONE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Mar 2021 16:43:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Mar 2021 16:43:46
Data point term sent to Coder DataPoint Un-verified.	System	17 Mar 2021 16:42:24
	lauren clement (b) (4)	17 Mar 2021 16:41:51
Coding entries removed.	lauren clement (b) (4)	17 Mar 2021 16:41:51
Signature has been broken.	lauren clement (b) (4)	17 Mar 2021 16:41:51
User entered 'Coenzyme Q10' reason for change: Data Entry Error	lauren clement (b) (4)	17 Mar 2021 16:41:51
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Aug 2020 19:02:15
	(b) (4)	
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 19:02:15
	(b) (4)	

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:56:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	11 Aug 2020 19:00:40
User entered 'MULTIVITAMIN'	Breanna Galibert (b) (4)	11 Aug 2020 19:00:34
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:05:50
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4) (b) (4)	10 Feb 2021 18:07:43
DataPoint Un-verified.	Angie Kean (b) (4) (b) (4)	10 Feb 2021 18:07:11
User entered 'Yes (Y)' reason for change: Per Query Resolution	Angie Kean (b) (4) (b) (4)	10 Feb 2021 18:07:11
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 12:52:36
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 19:00:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:56:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'GENERAL HEALTH'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 19:00:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:56:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
DataPoint Un-verified.	lauren clement (b) (4)	17 Mar 2021 16:41:51
Signature has been broken.	lauren clement (b) (4)	17 Mar 2021 16:41:51
User entered '10' reason for change: Data Entry Error	lauren clement (b) (4)	17 Mar 2021 16:41:51
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'I'	Breanna Galibert (b) (4)	11 Aug 2020 19:00:34
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:56:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
DataPoint Un-verified.	lauren clement (b) (4)	17 Mar 2021 16:41:51
Signature has been broken.	lauren clement (b) (4)	17 Mar 2021 16:41:51
User entered 'mg (mg)' reason for change: Data Entry Error	lauren clement (b) (4)	17 Mar 2021 16:41:51
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'tablet (TABLET)'	Breanna Galibert (b) (4)	11 Aug 2020 19:00:34
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered empty.	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 19:00:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:56:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'once daily (QD)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 19:00:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:56:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
	(b) (4)	
Signature has been broken.	Angie Kean (b) (4)	07 Apr 2021 16:43:32
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	11 Aug 2020 19:00:34
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 19:00:34



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:56:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered empty.	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 19:00:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:56:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:21:02
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 14:48:50
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 19:00:34
User entered 'UN UNK 2010'	Breanna Galibert (b) (4)	11 Aug 2020 19:00:34
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered '0'	Breanna Galibert (b) (4)	11 Aug 2020 19:00:34
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:56:12**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 19:00:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered empty.	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 19:00:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:56:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 19:00:34

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:56:12**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 19:00:34

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:56:12**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 19:00:34



**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:56:12**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 19:00:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:55
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:09
Data point term sent to Coder	System	20 Feb 2021 19:41:47
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:41:45
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 10:59:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 10:59:58
Data point term sent to Coder	System	10 Feb 2021 18:19:12
Coding entries removed.	Angie Kean (b) (4) (b) (4)	10 Feb 2021 18:18:48
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 20:04:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 20:04:30
Data point term sent to Coder	System	24 Nov 2020 16:03:38
Coding entries removed.	Angie Kean (b) (4) (b) (4)	24 Nov 2020 16:03:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:12

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 00:27:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 00:27:37
Data point term sent to Coder	System	12 Nov 2020 21:11:30
Coding entries removed.	Anya Penly (b) (4) (b) (4)	12 Nov 2020 21:11:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 18:57:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 18:57:35
Data point term sent to Coder	System	14 Oct 2020 18:29:15
Coding entries removed.	(b) (4), (b) (6)	14 Oct 2020 18:28:54
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 18:08:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 18:08:31
Data point term sent to Coder	System	09 Oct 2020 17:46:54
User entered 'ceftriaxone'	Breanna Galibert (b) (4) (b) (4)	09 Oct 2020 17:46:08

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:05:56
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'MEDICATIONS WAS GIVEN PRIOR TO PROSTATE BIOPSY FOR PROPHYLAXIS. ' (Site from DM).	Angie Kean (b) (4) (b) (4)	10 Feb 2021 18:19:10
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 07:38:51
Query 'US3812098 ' canceled (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 07:38:47
User opened query 'US3812098 ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 07:38:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	09 Oct 2020 17:46:08

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 18:05:58
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4)	10 Feb 2021 18:19:15
	(b) (4)	
DataPoint Un-verified.	Angie Kean (b) (4)	10 Feb 2021 18:18:48
	(b) (4)	
User entered 'PROSTATE BIOPSY' reason for change: New Information	Angie Kean (b) (4)	10 Feb 2021 18:18:48
	(b) (4)	
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 12:50:38
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:00:49
DataPoint Un-verified.	Anya Penly (b) (4)	12 Nov 2020 21:11:13
	(b) (4)	
User entered 'prostate cancer' reason for change:	Anya Penly (b) (4)	12 Nov 2020 21:11:13
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'PROSTATE BIOPSY for AE #1' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 18:28:54
User entered 'prostate biopsy'	Breanna Galibert (b) (4)	09 Oct 2020 17:46:08
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:55
User closed query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 13:33:11
Query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate. ' answered with 'data is correct per medical records' (Site from DM).	Angie Kean (b) (4) (b) (4)	09 Mar 2021 23:47:06
User opened query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 12:24:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MG, 1 G, etc) instead of injection count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Nov 2020 10:46:57
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MG, 1 G, etc) instead of injection count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4) (b) (4)	24 Nov 2020 16:00:29
DataPoint Un-verified.	Angie Kean (b) (4) (b) (4)	24 Nov 2020 16:00:05
User entered '2.4' reason for change: New Information	Angie Kean (b) (4) (b) (4)	24 Nov 2020 16:00:05

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:12

[Dose per administration](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MG, 1 G, etc) instead of injection count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 19:51:17
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'I'	Breanna Galibert (b) (4) (b) (4)	09 Oct 2020 17:46:08

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 18:06:00
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'DOSE IS CORRECT' (Site from DM).	Angie Kean (b) (4)	10 Feb 2021 18:19:20
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 12:51:09
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	24 Nov 2020 16:03:25
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	24 Nov 2020 16:00:05
DataPoint Un-verified.	Angie Kean (b) (4)	24 Nov 2020 16:00:05
User entered 'mg (mg)' reason for change: New Information	Angie Kean (b) (4)	24 Nov 2020 16:00:05
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'Other (OTHER)'	Breanna Galibert (b) (4)	09 Oct 2020 17:46:08



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:55
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Un-verified.	Angie Kean (b) (4)	24 Nov 2020 16:03:25
	(b) (4)	
User entered empty; reason for change Data Entry Error	Angie Kean (b) (4)	24 Nov 2020 16:03:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
	(b) (4)	
User entered 'injection'	Breanna Galibert (b) (4)	09 Oct 2020 17:46:08
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'once (ONCE)'	Breanna Galibert (b) (4)	09 Oct 2020 17:46:08
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered empty.	Breanna Galibert (b) (4)	09 Oct 2020 17:46:08
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:55
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Un-verified.	Angie Kean (b) (4)	24 Nov 2020 16:03:25
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Angie Kean (b) (4)	24 Nov 2020 16:03:25
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
	(b) (4)	
User entered 'Intramuscular (INTRAMUSCULAR)'	Breanna Galibert (b) (4)	09 Oct 2020 17:46:08
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered empty.	Breanna Galibert (b) (4)	09 Oct 2020 17:46:08
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered '02 Oct 2020'	Breanna Galibert (b) (4)	09 Oct 2020 17:46:08
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered '0'	Breanna Galibert (b) (4)	09 Oct 2020 17:46:08
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'No (N)'	Breanna Galibert (b) (4)	09 Oct 2020 17:46:08
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered '02 Oct 2020'	Breanna Galibert (b) (4)	09 Oct 2020 17:46:08
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'No (N)'	Breanna Galibert (b) (4)	09 Oct 2020 17:46:08
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:55
User entered empty.	System	09 Oct 2020 17:46:08

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:55
User entered empty.	System	09 Oct 2020 17:46:08

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:55
User entered empty.	System	09 Oct 2020 17:46:08

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Feb 2021 20:13:06
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Feb 2021 20:13:06
	(b) (4)	
Data point term sent to Coder	System	20 Feb 2021 19:41:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 14:32:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 14:32:40
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 14:30:59
User entered 'tylenol'	Any Penly (b) (4)	21 Oct 2020 14:30:42
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:57
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'No (N)'	Any Penly (b) (4)	21 Oct 2020 14:30:42
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:57
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 18:06:08
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria.' answered with 'SOLICITED EVENT IS MARKED AS YES' (Site from DM).	Angie Kean (b) (4)	10 Feb 2021 18:32:57



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:12

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 12:55:34
	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'pain at injection site'	Any Penly (b) (4)	21 Oct 2020 14:30:42
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:57
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered '500'	Anyia Penly (b) (4)	21 Oct 2020 14:30:42
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:57
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'mg (mg)'	Anyia Penly (b) (4)	21 Oct 2020 14:30:42
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:57
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered empty.	Anyia Penly (b) (4)	21 Oct 2020 14:30:42
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:57
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'once daily (QD)'	Anyia Penly (b) (4)	21 Oct 2020 14:30:42
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:57
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered empty.	Anyia Penly (b) (4)	21 Oct 2020 14:30:42
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:57
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'Oral (ORAL)'	Anyia Penly (b) (4)	21 Oct 2020 14:30:42
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:57
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered empty.	Anyia Penly (b) (4)	21 Oct 2020 14:30:42
	(b) (4)	



US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:57
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered '10 Sep 2020'	Anyia Penly (b) (4)	21 Oct 2020 14:30:42
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:57
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered '0'	Anyia Penly (b) (4)	21 Oct 2020 14:30:42
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:57
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'No (N)'	Anyia Penly (b) (4)	21 Oct 2020 14:30:42
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:57
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered '11 Sep 2020'	Anyia Penly (b) (4)	21 Oct 2020 14:30:42
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:57
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'Yes (Y)'	Anya Penly (b) (4)	21 Oct 2020 14:30:42
	(b) (4)	

US3812098

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:56:12**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:57
User entered '1'	System	21 Oct 2020 14:30:42

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:57
User entered '1'	System	21 Oct 2020 14:30:42

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:57
User entered '804 (804)'	System	21 Oct 2020 14:30:42



US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Feb 2021 20:13:16
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Feb 2021 20:13:16
	(b) (4)	
Data point term sent to Coder	System	20 Feb 2021 19:41:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 14:34:19
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 14:34:19
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 14:33:04
User entered 'tylenol'	Any Penly (b) (4)	21 Oct 2020 14:32:05
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'No (N)'	Anyia Penly (b) (4)	21 Oct 2020 14:32:05
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'bilateral hip pain and neck pain'	Anyia Penly (b) (4)	21 Oct 2020 14:32:05
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered '500'	Anyia Penly (b) (4)	21 Oct 2020 14:32:05
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'mg (mg)'	Anyia Penly (b) (4)	21 Oct 2020 14:32:05
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered empty.	Anyia Penly (b) (4)	21 Oct 2020 14:32:05
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'once daily (QD)'	Anyia Penly (b) (4)	21 Oct 2020 14:32:05
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered empty.	Anyia Penly (b) (4)	21 Oct 2020 14:32:05
	(b) (4)	



US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'Oral (ORAL)'	Anyia Penly (b) (4)	21 Oct 2020 14:32:05
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered empty.	Anyia Penly (b) (4)	21 Oct 2020 14:32:05
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered '24 Sep 2020'	Anyia Penly (b) (4)	21 Oct 2020 14:32:05
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered '0'	Anyia Penly (b) (4)	21 Oct 2020 14:32:05
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'No (N)'	Anyia Penly (b) (4)	21 Oct 2020 14:32:05
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered '24 Sep 2020'	Anyia Penly (b) (4)	21 Oct 2020 14:32:05
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'No (N)'	Anyia Penly (b) (4)	21 Oct 2020 14:32:05
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:00
User entered '1'	System	21 Oct 2020 14:32:05



US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:00
User entered '1'	System	21 Oct 2020 14:32:05

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:00
User entered '804 (804)'	System	21 Oct 2020 14:32:05

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:28:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:28:54
Data point term sent to Coder	System	20 Feb 2021 19:41:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:21:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 15:19:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 15:19:32
Data point term sent to Coder	System	21 Oct 2020 14:33:04
User entered 'aspirin'	Anyia Penly (b) (4) (b) (4)	21 Oct 2020 14:32:55

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:01
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'No (N)'	Anyia Penly (b) (4)	21 Oct 2020 14:32:55
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:01
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'bilateral hip pain and neck pain'	Anyia Penly (b) (4)	21 Oct 2020 14:32:55
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:01
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered '325'	Anyia Penly (b) (4)	21 Oct 2020 14:32:55
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:01
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'mg (mg)'	Anyia Penly (b) (4)	21 Oct 2020 14:32:55
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:01
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered empty.	Anyia Penly (b) (4)	21 Oct 2020 14:32:55
	(b) (4)	



US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:01
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'once daily (QD)'	Anyia Penly (b) (4)	21 Oct 2020 14:32:55
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:01
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered empty.	Anyia Penly (b) (4)	21 Oct 2020 14:32:55
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:01
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'Oral (ORAL)'	Anyia Penly (b) (4)	21 Oct 2020 14:32:55
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:01
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered empty.	Anyia Penly (b) (4)	21 Oct 2020 14:32:55
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:01
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered '24 Sep 2020'	Anyia Penly (b) (4)	21 Oct 2020 14:32:55
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:01
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered '0'	Anyia Penly (b) (4)	21 Oct 2020 14:32:55
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:01
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'No (N)'	Anyia Penly (b) (4)	21 Oct 2020 14:32:55
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:01
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered '24 Sep 2020'	Anyia Penly (b) (4)	21 Oct 2020 14:32:55
	(b) (4)	



US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:01
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'No (N)'	Anyia Penly (b) (4)	21 Oct 2020 14:32:55
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:56:12**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:01
User entered '1'	System	21 Oct 2020 14:32:55

US3812098

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:56:12**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:01
User entered '1'	System	21 Oct 2020 14:32:55

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:01
User entered '804 (804)'	System	21 Oct 2020 14:32:55

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:05
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Feb 2021 20:13:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4)	20 Feb 2021 20:13:04
Data point term sent to Coder	System	20 Feb 2021 19:41:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4)	23 Nov 2020 22:43:05
User closed query 'please correct spelling to prednisone' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 22:43:01
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Nov 2020 06:36:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4)	22 Nov 2020 06:36:51
Data point term sent to Coder	System	20 Nov 2020 17:49:19
Query 'please correct spelling to prednisone' answered with 'UPDATED' (Site from CRA).	Angie Kean (b) (4)	20 Nov 2020 17:49:14
Coding entries removed.	(b) (4)	20 Nov 2020 17:49:08
User entered 'PREDNISONE' reason for change: Data Entry Error	Angie Kean (b) (4)	20 Nov 2020 17:49:08
Query 'prednisone is exclusionary for dose >20mg (Excl#12). Please file ePIP and PD.' canceled (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 16:12:37

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:12

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 07:53:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	17 Nov 2020 07:53:54
User opened query 'prednisone is exclusionary for dose >20mg (Excl#12). Please file ePIP and PD.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 18:19:29
User opened query 'please correct spelling to prednisone' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 18:01:26
Data point term sent to Coder	System	16 Nov 2020 15:41:23
User entered 'predinsone'	Breanna Galibert (b) (4)	16 Nov 2020 15:40:39
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:05
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:01:56
User entered 'No (N)'	Breanna Galibert (b) (4)	16 Nov 2020 15:40:39
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:05
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:01:58
User entered 'bilateral hip pain'	Breanna Galibert (b) (4)	16 Nov 2020 15:40:39
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:05
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:02:00
User entered '50'	Breanna Galibert (b) (4)	16 Nov 2020 15:40:39
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:05
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:02:05
User entered 'mg (mg)'	Breanna Galibert (b) (4)	16 Nov 2020 15:40:39
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:05
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:02:07
User entered empty.	Breanna Galibert (b) (4)	16 Nov 2020 15:40:39
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:05
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:02:09
User entered 'once daily (QD)'	Breanna Galibert (b) (4)	16 Nov 2020 15:40:39
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:05
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:02:13
User entered empty.	Breanna Galibert (b) (4)	16 Nov 2020 15:40:39
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:05
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:02:15
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	16 Nov 2020 15:40:39
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:05
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:02:17
User entered empty.	Breanna Galibert (b) (4)	16 Nov 2020 15:40:39
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:05
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:02:19
User entered '04 Nov 2020'	Breanna Galibert (b) (4)	16 Nov 2020 15:40:39
	(b) (4)	



US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:05
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:02:27
User entered '0'	Breanna Galibert (b) (4)	16 Nov 2020 15:40:39
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:05
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:02:23
User entered 'No (N)'	Breanna Galibert (b) (4)	16 Nov 2020 15:40:39
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:05
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:02:25
User entered '13 Nov 2020'	Breanna Galibert (b) (4)	16 Nov 2020 15:40:39
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:05
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:06:26
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification.' answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4) (b) (4)	10 Feb 2021 18:33:40
DataPoint Un-verified.	Angie Kean (b) (4) (b) (4)	10 Feb 2021 18:33:16
User entered 'No (N)' reason for change: Data Entry Error	Angie Kean (b) (4) (b) (4)	10 Feb 2021 18:33:16

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 12:55:00
	(b) (4), (b) (6)	16 Nov 2020 18:02:29
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	16 Nov 2020 15:40:39
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:56:12**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:05
User entered '1'	System	16 Nov 2020 15:40:39

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:05
User entered '1'	System	16 Nov 2020 15:40:39

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:05
User entered '804 (804)'	System	16 Nov 2020 15:40:39



US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:56:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:06
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE POLYSACCH 23V, PRODUCTSYNONYM: PNEUMOVAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Feb 2021 20:27:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	20 Feb 2021 20:27:59
Data point term sent to Coder	System	20 Feb 2021 19:41:48
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4)	16 Nov 2020 18:26:15
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE POLYSACCH 23V, PRODUCTSYNONYM: PNEUMOVAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 15:43:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	16 Nov 2020 15:43:43
Data point term sent to Coder	System	16 Nov 2020 15:42:24
User entered 'pneumovax'	Breanna Galibert (b) (4)	16 Nov 2020 15:41:37
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:56:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:06
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 18:06:33
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4)	10 Feb 2021 18:49:04
	(b) (4)	
DataPoint Un-verified.	Angie Kean (b) (4)	10 Feb 2021 18:34:05
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Angie Kean (b) (4)	10 Feb 2021 18:34:05
	(b) (4)	
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 12:53:06
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:26:18
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	16 Nov 2020 15:41:37
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:56:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:26:20
User entered 'immunization'	Breanna Galibert (b) (4)	16 Nov 2020 15:41:37
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:56:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:26:54
User entered '0.5'	Breanna Galibert (b) (4)	16 Nov 2020 15:41:37
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:56:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:26:55
User entered 'mL (mL)'	Breanna Galibert (b) (4)	16 Nov 2020 15:41:37
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:56:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:26:57
User entered empty.	Breanna Galibert (b) (4)	16 Nov 2020 15:41:37
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:56:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:27:01
User entered 'once (ONCE)'	Breanna Galibert (b) (4)	16 Nov 2020 15:41:37
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:56:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:27:00
User entered empty.	Breanna Galibert (b) (4)	16 Nov 2020 15:41:37
	(b) (4)	



US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:56:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:27:03
User entered 'Intramuscular (INTRAMUSCULAR)'	Breanna Galibert (b) (4)	16 Nov 2020 15:41:37
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:56:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:27:05
User entered empty.	Breanna Galibert (b) (4)	16 Nov 2020 15:41:37
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:56:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:27:07
User entered '04 Nov 2020'	Breanna Galibert (b) (4)	16 Nov 2020 15:41:37
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:56:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:27:08
User entered '0'	Breanna Galibert (b) (4)	16 Nov 2020 15:41:37
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:56:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:27:11
User entered 'No (N)'	Breanna Galibert (b) (4)	16 Nov 2020 15:41:37
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:27:12
User entered '04 Nov 2020'	Breanna Galibert (b) (4)	16 Nov 2020 15:41:37
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:56:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:27:15
User entered 'No (N)'	Breanna Galibert (b) (4)	16 Nov 2020 15:41:37
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:56:12**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:06
User entered empty.	System	16 Nov 2020 15:41:37



US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:56:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:06
User entered empty.	System	16 Nov 2020 15:41:37

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:56:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:06
User entered empty.	System	16 Nov 2020 15:41:37

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:56:12

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:12:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:12:54
Data point term sent to Coder	System	20 Feb 2021 19:41:48
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:41:45
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 06:12:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 06:12:51
Data point term sent to Coder	System	04 Dec 2020 21:25:04
User entered 'Vitamin B-12'	Angie Kean (b) (4) (b) (4)	04 Dec 2020 21:24:33

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:56:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	04 Dec 2020 21:24:33
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:56:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'B-12 deficiency'	Angie Kean (b) (4)	04 Dec 2020 21:24:33
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:56:12**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '1000'	Angie Kean (b) (4)	04 Dec 2020 21:24:33
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:56:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'ug (ug)'	Angie Kean (b) (4)	04 Dec 2020 21:24:33
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:56:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	04 Dec 2020 21:24:33
	(b) (4)	



US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:56:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'once daily (QD)'	Angie Kean (b) (4)	04 Dec 2020 21:24:33
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:56:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	04 Dec 2020 21:24:33
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:56:12**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Oral (ORAL)'	Angie Kean (b) (4)	04 Dec 2020 21:24:33
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:56:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	04 Dec 2020 21:24:33
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:56:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'un UNK 2019'	Angie Kean (b) (4)	04 Dec 2020 21:24:33
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:56:12**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '0'	Angie Kean (b) (4)	04 Dec 2020 21:24:33
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:56:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Yes (Y)'	Angie Kean (b) (4)	04 Dec 2020 21:24:33
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	04 Dec 2020 21:24:33
	(b) (4)	



**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:56:12**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	04 Dec 2020 21:24:33
	(b) (4)	

US3812098

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:56:12**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 21:24:33

US3812098

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:56:12**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 21:24:33

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:56:12**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Dec 2020 21:24:33

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:56:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:11
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ANTINEOPLASTIC AGENTS, ATC: OTHER ANTINEOPLASTIC AGENTS, ATC: OTHER ANTINEOPLASTIC AGENTS, PRODUCT: LENALIDOMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Feb 2021 20:12:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	20 Feb 2021 20:12:55
Data point term sent to Coder	System	20 Feb 2021 19:41:48
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ANTINEOPLASTIC AGENTS, ATC: OTHER ANTINEOPLASTIC AGENTS, ATC: OTHER ANTINEOPLASTIC AGENTS, PRODUCT: LENALIDOMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 10:59:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	04 Feb 2021 10:59:50
Data point term sent to Coder	System	03 Feb 2021 19:47:48
Coding entries removed.	Breanna Galibert (b) (4)	03 Feb 2021 19:47:16
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ANTINEOPLASTIC AGENTS, ATC: OTHER ANTINEOPLASTIC AGENTS, ATC: OTHER ANTINEOPLASTIC AGENTS, PRODUCT: LENALIDOMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 00:40:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	18 Dec 2020 00:40:45
Data point term sent to Coder	System	10 Dec 2020 22:23:44
User entered 'LEHALIDOMIDE'	Heather Cherniawski (b) (4)	10 Dec 2020 22:23:11

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**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:56:12**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Heather Cherniawski	10 Dec 2020 22:23:11
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:56:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'prostate cancer' reason for change:	Breanna Galibert (b) (4)	03 Feb 2021 19:47:16
Data Entry Error	(b) (4)	
User entered 'BONE CANCER'	Heather Cherniawski	10 Dec 2020 22:23:11
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:56:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '25'	Heather Cherniawski	10 Dec 2020 22:23:11
	(b) (4)	



US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:56:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'mg (mg)'	Heather Cherniawski	10 Dec 2020 22:23:11
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:56:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Dec 2020 22:23:11
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:56:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'once daily (QD)'	Heather Cherniawski	10 Dec 2020 22:23:11
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:56:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Dec 2020 22:23:11
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:56:12**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Oral (ORAL)'	Heather Cherniawski	10 Dec 2020 22:23:11
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:56:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Dec 2020 22:23:11
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:56:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:11
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Signature has been broken.	Angie Kean (b) (4)	07 Apr 2021 16:46:40
	(b) (4)	
User entered '04 Dec 2020' reason for change: New Information	Angie Kean (b) (4)	07 Apr 2021 16:46:40
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '08 Dec 2020'	Heather Cherniawski	10 Dec 2020 22:23:11
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:56:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '0'	Heather Cherniawski	10 Dec 2020 22:23:11
	(b) (4)	



US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:56:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:11
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Signature has been broken.	Angie Kean (b) (4)	07 Apr 2021 16:46:40
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Angie Kean (b) (4)	07 Apr 2021 16:46:40
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Yes (Y)'	Heather Cherniawski	10 Dec 2020 22:23:11
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:11
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Signature has been broken.	Angie Kean (b) (4)	07 Apr 2021 16:46:40
	(b) (4)	
User entered '08 Dec 2020' reason for change: New Information	Angie Kean (b) (4)	07 Apr 2021 16:46:40
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Dec 2020 22:23:11
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:56:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Heather Cherniawski	10 Dec 2020 22:23:11
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:56:12**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:11
User entered '1'	System	10 Dec 2020 22:23:11

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:56:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:11
User entered '1'	System	10 Dec 2020 22:23:11

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:56:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:11
User entered '804 (804)'	System	10 Dec 2020 22:23:11

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:56:12

Name of Medication

Audit	User	Time (GMT)
User closed query "'Per MM, please confirm if this is prohibited medication per protocol section 6.4.3 '''Concomitant Medications and Vaccines that May Lead to the Elimination of a Participant from Per-Protocol Analyses. ' (Site from DM).	(b) (4), (b) (6)	27 Apr 2021 07:26:24
Query "'Per MM, please confirm if this is prohibited medication per protocol section 6.4.3 '''Concomitant Medications and Vaccines that May Lead to the Elimination of a Participant from Per-Protocol Analyses. ' answered with 'Per PI, subject was enrolled into study prior to receiving concomitant treatment, which is not exclusionary. Subject was unblinded and found to have already received IP as well, prior to treatment. ' (Site from DM).	Angie Kean (b) (4) (b) (4)	06 Apr 2021 22:12:56
User opened query "'Per MM, please confirm if this is prohibited medication per protocol section 6.4.3 '''Concomitant Medications and Vaccines that May Lead to the Elimination of a Participant from Per-Protocol Analyses. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 15:06:22
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:01
Data point term sent to Coder	System	20 Feb 2021 19:41:48
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:41:45

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:56:12

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 10:40:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 10:40:44
Data point term sent to Coder Coding entries removed.	System Breanna Galibert (b) (4)	03 Feb 2021 19:47:48 03 Feb 2021 19:47:39
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 07:14:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 07:14:02
Data point term sent to Coder User entered 'DEXAMETHASONE'	System Heather Cherniawski (b) (4)	10 Dec 2020 22:27:46 10 Dec 2020 22:27:39



US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:56:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Heather Cherniawski	10 Dec 2020 22:27:39
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:56:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'multiple myeloma' reason for change: New Information	Breanna Galibert (b) (4)	03 Feb 2021 19:47:39
	(b) (4)	
User entered 'BONE CANCER'	Heather Cherniawski	10 Dec 2020 22:27:39
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:56:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '20'	Heather Cherniawski	10 Dec 2020 22:27:39
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:56:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'mg (mg)'	Heather Cherniawski	10 Dec 2020 22:27:39
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:56:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Dec 2020 22:27:39
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:56:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'other (OTHER)'	Heather Cherniawski	10 Dec 2020 22:27:39
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:56:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'TWICE A WEEK'	Heather Cherniawski	10 Dec 2020 22:27:39
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:56:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Oral (ORAL)'	Heather Cherniawski	10 Dec 2020 22:27:39
	(b) (4)	



US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:56:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Dec 2020 22:27:39
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:56:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '08 Dec 2020'	Heather Cherniawski	10 Dec 2020 22:27:39
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:56:12

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '0'	Heather Cherniawski	10 Dec 2020 22:27:39
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:56:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Yes (Y)'	Heather Cherniawski	10 Dec 2020 22:27:39
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Dec 2020 22:27:39
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:56:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Heather Cherniawski	10 Dec 2020 22:27:39
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:56:12**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Dec 2020 22:27:39

US3812098

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:56:12**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Dec 2020 22:27:39



**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:56:12**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Dec 2020 22:27:39

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:56:12

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ANTINEOPLASTIC AGENTS, ATC: OTHER ANTINEOPLASTIC AGENTS, ATC: OTHER ANTINEOPLASTIC AGENTS, PRODUCT: LENALIDOMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:18:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:18:54
Data point term sent to Coder	System	09 Mar 2021 23:48:09
Coding entries removed.	Angie Kean (b) (4) (b) (4)	09 Mar 2021 23:47:47
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ANTINEOPLASTIC AGENTS, ATC: OTHER ANTINEOPLASTIC AGENTS, ATC: OTHER ANTINEOPLASTIC AGENTS, PRODUCT: LENALIDOMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:13
Data point term sent to Coder	System	20 Feb 2021 19:41:48
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:41:45
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ANTINEOPLASTIC AGENTS, ATC: OTHER ANTINEOPLASTIC AGENTS, ATC: OTHER ANTINEOPLASTIC AGENTS, PRODUCT: LENALIDOMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 10:58:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 10:58:51
Data point term sent to Coder	System	03 Feb 2021 19:48:49
Coding entries removed.	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:47:52

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:56:12

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ANTINEOPLASTIC AGENTS, ATC: OTHER ANTINEOPLASTIC AGENTS, ATC: OTHER ANTINEOPLASTIC AGENTS, PRODUCT: LENALIDOMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 00:43:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 00:43:52
Data point term sent to Coder	System	10 Dec 2020 22:29:46
User entered 'LENALIDOMIDE'	Heather Cherniawski (b) (4)	10 Dec 2020 22:29:20

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:56:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Heather Cherniawski	10 Dec 2020 22:29:20
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:56:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'multiple myeloma' reason for change: New Information	Breanna Galibert (b) (4)	03 Feb 2021 19:47:52
	(b) (4)	
User entered 'BONE CANCER'	Heather Cherniawski	10 Dec 2020 22:29:20
	(b) (4)	

US3812098

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:56:12**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'UNK'	Heather Cherniawski	10 Dec 2020 22:29:20
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:56:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Other (OTHER)'	Heather Cherniawski	10 Dec 2020 22:29:20
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:56:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'UNK'	Heather Cherniawski	10 Dec 2020 22:29:20
	(b) (4)	



US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:56:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'every week (QS)'	Heather Cherniawski	10 Dec 2020 22:29:20
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:56:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Dec 2020 22:29:20
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:56:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
	(b) (4), (b) (6)	12 Mar 2021 13:33:48
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	Angie Kean (b) (4)	09 Mar 2021 23:47:53
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'updated' (Site from DM).	Angie Kean (b) (4)	09 Mar 2021 23:47:47
Signature has been broken.	Angie Kean (b) (4)	09 Mar 2021 23:47:47
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Angie Kean (b) (4)	23 Feb 2021 21:22:16
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User signature succeeded.	Heather Cherniawski (b) (4)	10 Dec 2020 22:29:20

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:56:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Dec 2020 22:29:20
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:56:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '08 Dec 2020'	Heather Cherniawski	10 Dec 2020 22:29:20
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:56:12

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '0'	Heather Cherniawski	10 Dec 2020 22:29:20
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:56:12**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Yes (Y)'	Heather Cherniawski	10 Dec 2020 22:29:20
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Dec 2020 22:29:20
	(b) (4)	



US3812098

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:56:12**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Heather Cherniawski	10 Dec 2020 22:29:20
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:56:12**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Dec 2020 22:29:20

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:56:12**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Dec 2020 22:29:20

US3812098

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:56:12**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	10 Dec 2020 22:29:20

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:56:12

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: ACICLOVIR, PRODUCTSYNONYM: ACYCLOVIR [ACICLOVIR] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:12:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:12:59
Data point term sent to Coder	System	20 Feb 2021 19:41:48
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:41:45
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: ACICLOVIR, PRODUCTSYNONYM: ACYCLOVIR [ACICLOVIR] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 09:27:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 09:27:43
Data point term sent to Coder	System	03 Feb 2021 19:48:49
Coding entries removed.	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:48:03
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: ACICLOVIR, PRODUCTSYNONYM: ACYCLOVIR [ACICLOVIR] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 23:38:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 23:38:54

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:56:12**

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	10 Dec 2020 22:30:47
User entered 'ACYCLOVIR'	Heather Cherniawski	10 Dec 2020 22:30:42
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:56:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Heather Cherniawski	10 Dec 2020 22:30:42
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:56:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'multiple myeloma' reason for change: New Information	Breanna Galibert (b) (4)	03 Feb 2021 19:48:03
	(b) (4)	
User entered 'BONE CANCER'	Heather Cherniawski	10 Dec 2020 22:30:42
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:56:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '200'	Heather Cherniawski	10 Dec 2020 22:30:42
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:56:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'mg (mg)'	Heather Cherniawski	10 Dec 2020 22:30:42
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:56:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Dec 2020 22:30:42
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:56:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'twice daily (BID)'	Heather Cherniawski	10 Dec 2020 22:30:42
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:56:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Dec 2020 22:30:42
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:56:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Oral (ORAL)'	Heather Cherniawski	10 Dec 2020 22:30:42
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:56:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Dec 2020 22:30:42
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:56:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '08 Dec 2020'	Heather Cherniawski	10 Dec 2020 22:30:42
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:56:12

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '0'	Heather Cherniawski	10 Dec 2020 22:30:42
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:56:12**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Yes (Y)'	Heather Cherniawski	10 Dec 2020 22:30:42
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Dec 2020 22:30:42
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:56:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Heather Cherniawski	10 Dec 2020 22:30:42
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:56:12**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	10 Dec 2020 22:30:42

US3812098

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:56:12**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Dec 2020 22:30:42

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:56:12**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Dec 2020 22:30:42

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:56:12

[Name of Medication](#)

Audit	User	Time (GMT)
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: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:08
Data point term sent to Coder	System	20 Feb 2021 19:41:50
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:41:45
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: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 19:49:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 19:49:27
Data point term sent to Coder	System	03 Feb 2021 19:48:51
Coding entries removed.	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:48:15
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: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 22:32:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 22:32:57
Data point term sent to Coder	System	10 Dec 2020 22:31:48
User entered 'NORCO'	Heather Cherniawski (b) (4)	10 Dec 2020 22:31:46

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:56:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Heather Cherniawski	10 Dec 2020 22:31:46
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:56:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'multiple myeloma' reason for change: New Information	Breanna Galibert (b) (4)	03 Feb 2021 19:48:15
	(b) (4)	
User entered 'BONE CANCER'	Heather Cherniawski	10 Dec 2020 22:31:46
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:56:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '5/325'	Heather Cherniawski	10 Dec 2020 22:31:46
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:56:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'mg (mg)'	Heather Cherniawski	10 Dec 2020 22:31:46
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:56:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Dec 2020 22:31:46
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:56:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'as needed (PRN)'	Heather Cherniawski	10 Dec 2020 22:31:46
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:56:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Dec 2020 22:31:46
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:56:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Oral (ORAL)'	Heather Cherniawski	10 Dec 2020 22:31:46
	(b) (4)	



US3812098

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:56:12**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Dec 2020 22:31:46
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:56:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:07:50
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4) (b) (4)	10 Feb 2021 18:50:23
User entered '08 Dec 2020' reason for change: Data Entry Error	Angie Kean (b) (4) (b) (4)	10 Feb 2021 18:50:16
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 07:39:11
User entered '08 Nov 2020'	Heather Cherniawski (b) (4)	10 Dec 2020 22:31:46

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:56:12

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '0'	Heather Cherniawski	10 Dec 2020 22:31:46
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:56:12**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Yes (Y)'	Heather Cherniawski	10 Dec 2020 22:31:46
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Dec 2020 22:31:46
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:56:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Heather Cherniawski	10 Dec 2020 22:31:46
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:56:12**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Dec 2020 22:31:46

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:56:12**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Dec 2020 22:31:46



**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:56:12**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Dec 2020 22:31:46

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:56:12

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 04:19:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 04:19:30
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPRIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 04:14:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 04:14:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPRIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:14
Data point term sent to Coder	System	20 Feb 2021 19:41:50
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:41:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPRIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 12:01:45

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:56:12

Name of Medication

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder Coding entries removed.	Coder Import (b) (4) (b) (4) System Breanna Galibert (b) (4) (b) (4)	04 Feb 2021 12:01:45  03 Feb 2021 19:48:49 03 Feb 2021 19:48:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 23:39:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'ASPRIN'	Coder Import (b) (4) (b) (4) System Heather Cherniawski (b) (4)	10 Dec 2020 23:39:55  10 Dec 2020 22:33:48 10 Dec 2020 22:32:58

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:56:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Heather Cherniawski	10 Dec 2020 22:32:58
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:56:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'multiple myeloma' reason for change:	Breanna Galibert (b) (4)	03 Feb 2021 19:48:37
New Information	(b) (4)	
User entered 'BONE CANCER'	Heather Cherniawski	10 Dec 2020 22:32:58
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:56:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '81'	Heather Cherniawski	10 Dec 2020 22:32:58
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:56:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'mg (mg)'	Heather Cherniawski	10 Dec 2020 22:32:58
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:56:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Dec 2020 22:32:58
	(b) (4)	



US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:56:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'once daily (QD)'	(b) (4) Heather Cherniawski (b) (4)	10 Dec 2020 22:32:58

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:56:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Dec 2020 22:32:58
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:56:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Oral (ORAL)'	Heather Cherniawski	10 Dec 2020 22:32:58
	(b) (4)	

US3812098

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:56:12**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Dec 2020 22:32:58
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:56:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '08 Dec 2020'	Heather Cherniawski	10 Dec 2020 22:32:58
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:56:12

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '0'	Heather Cherniawski	10 Dec 2020 22:32:58
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:56:12**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Yes (Y)'	Heather Cherniawski	10 Dec 2020 22:32:58
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Dec 2020 22:32:58
	(b) (4)	



US3812098

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:56:12**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Heather Cherniawski	10 Dec 2020 22:32:58
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:56:12**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Dec 2020 22:32:58

US3812098

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:56:12**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Dec 2020 22:32:58

US3812098

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:56:12**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Dec 2020 22:32:58

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:56:12

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: PROCHLORPERAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:12
Data point term sent to Coder	System	20 Feb 2021 19:41:49
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:41:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: PROCHLORPERAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 11:49:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 11:49:45
Data point term sent to Coder	System	03 Feb 2021 19:49:53
Coding entries removed.	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:48:56
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: PROCHLORPERAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 00:28:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 00:28:50
Data point term sent to Coder	System	10 Dec 2020 22:35:49
User entered 'PROCHLORPERAZINE'	Heather Cherniawski (b) (4)	10 Dec 2020 22:35:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:56:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Heather Cherniawski	10 Dec 2020 22:35:14
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:56:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'multiple myeloma' reason for change: New Information	Breanna Galibert (b) (4)	03 Feb 2021 19:48:56
	(b) (4)	
User entered 'BONE CANCER'	Heather Cherniawski	10 Dec 2020 22:35:14
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:56:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '10'	Heather Cherniawski	10 Dec 2020 22:35:14
	(b) (4)	



US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:56:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'mg (mg)'	Heather Cherniawski	10 Dec 2020 22:35:14
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:56:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Dec 2020 22:35:14
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:56:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'as needed (PRN)'	Heather Cherniawski	10 Dec 2020 22:35:14
	(b) (4)	

US3812098

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:56:12**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Dec 2020 22:35:14
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:56:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Oral (ORAL)'	Heather Cherniawski	10 Dec 2020 22:35:14
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:56:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Dec 2020 22:35:14
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:56:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '08 Dec 2020'	Heather Cherniawski	10 Dec 2020 22:35:14
	(b) (4)	

US3812098

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:56:12**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '0'	Heather Cherniawski	10 Dec 2020 22:35:14
	(b) (4)	



**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:56:12**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Yes (Y)'	Heather Cherniawski	10 Dec 2020 22:35:14
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Dec 2020 22:35:14
	(b) (4)	

US3812098

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:56:12**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Heather Cherniawski	10 Dec 2020 22:35:14
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:56:12**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Dec 2020 22:35:14

US3812098

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:56:12**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Dec 2020 22:35:14

US3812098

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:56:12**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Dec 2020 22:35:14

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:56:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:16
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: TIZANIDINE HYDROCHLORIDE, PRODUCTSYNONYM: ZANAFLEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:17
Data point term sent to Coder User signature succeeded.	System Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:41:52 20 Feb 2021 19:41:45
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: TIZANIDINE HYDROCHLORIDE, PRODUCTSYNONYM: ZANAFLEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 19:50:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 19:50:27
Data point term sent to Coder User entered 'zanaflex'	System Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:49:54 03 Feb 2021 19:49:41

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:56:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Feb 2021 19:49:41
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:56:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'multiple myeloma'	Breanna Galibert (b) (4)	03 Feb 2021 19:49:41
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:56:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '2'	Breanna Galibert (b) (4)	03 Feb 2021 19:49:41
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:56:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'mg (mg)'	Breanna Galibert (b) (4)	03 Feb 2021 19:49:41
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:56:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	03 Feb 2021 19:49:41
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:56:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'other (OTHER)'	Breanna Galibert (b) (4)	03 Feb 2021 19:49:41
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:56:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'every 8 hours as needed'	Breanna Galibert (b) (4)	03 Feb 2021 19:49:41
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:56:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	03 Feb 2021 19:49:41
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:56:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	03 Feb 2021 19:49:41
	(b) (4)	



US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:56:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:16
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE (01Dec2020). Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 18:39:16
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE (01Dec2020). Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' answered with 'subject was symptomatic for multiple myeloma prior to confirmed diagnosis which was 24 NOV 2020. Per monitor, start date was changed to reflect the date of confirming biopsy. subject was treated for symptoms prior to this date. ' (Site from DM).	Angie Kean (b) (4) (b) (4)	07 Apr 2021 16:36:05
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE (01Dec2020). Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 21:23:42
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:41:45
User entered '20 Nov 2020'	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:49:41

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:56:12**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	03 Feb 2021 19:49:41
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:56:12**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Feb 2021 19:49:41
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '02 Dec 2020'	Breanna Galibert (b) (4)	03 Feb 2021 19:49:41
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:56:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Feb 2021 19:49:41
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:56:12**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:16
User entered empty.	System	03 Feb 2021 19:49:41

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:56:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:16
User entered empty.	System	03 Feb 2021 19:49:41

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:56:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:16
User entered empty.	System	03 Feb 2021 19:49:41



US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:56:12

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: CANNABIDIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:28:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:28:56
Data point term sent to Coder	System	20 Feb 2021 19:41:52
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:41:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: CANNABIDIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 00:39:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 00:39:39
Data point term sent to Coder	System	03 Feb 2021 19:51:57
User entered 'cannabidiol cbd'	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:50:58

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:56:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Feb 2021 19:50:58
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:56:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'prostate cancer and multiple myeloma'	Breanna Galibert (b) (4)	03 Feb 2021 19:50:58
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:56:12

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 18:42:21
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'unfortunately all that is disclosed to us is 1 tablet' (Site from DM).	Angie Kean (b) (4) (b) (4)	07 Apr 2021 16:47:27
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 21:24:05
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:41:45
User entered 'I'	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:50:58

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:56:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'tablet (TABLET)'	Breanna Galibert (b) (4)	03 Feb 2021 19:50:58
	(b) (4)	

US3812098

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:56:12**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	03 Feb 2021 19:50:58
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:56:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'once daily (QD)'	Breanna Galibert (b) (4)	03 Feb 2021 19:50:58
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:56:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	03 Feb 2021 19:50:58
	(b) (4)	



US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:56:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	03 Feb 2021 19:50:58
	(b) (4)	

US3812098

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:56:12**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	03 Feb 2021 19:50:58
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:56:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'un Oct 2020'	Breanna Galibert (b) (4)	03 Feb 2021 19:50:58
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:56:12

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	03 Feb 2021 19:50:58
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:56:12**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	03 Feb 2021 19:50:58
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	03 Feb 2021 19:50:58
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:56:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Feb 2021 19:50:58
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:56:12**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 19:50:58



**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:56:12**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 19:50:58

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:56:12**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Feb 2021 19:50:58

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:56:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:19
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:28:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:28:56
Data point term sent to Coder	System	20 Feb 2021 19:41:52
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:41:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 19:53:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 19:53:27
Data point term sent to Coder	System	03 Feb 2021 19:52:59
User entered 'vitamin d3'	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:51:58

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:56:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:19
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Feb 2021 19:51:58
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:56:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:19
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'prostate cancer and multiple myeloma'	Breanna Galibert (b) (4)	03 Feb 2021 19:51:58
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:56:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:19
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'I'	Breanna Galibert (b) (4)	03 Feb 2021 19:51:58
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:56:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:19
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'tablet (TABLET)'	Breanna Galibert (b) (4)	03 Feb 2021 19:51:58
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:56:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:19
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	03 Feb 2021 19:51:58
	(b) (4)	



US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:56:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:19
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'other (OTHER)'	Breanna Galibert (b) (4)	03 Feb 2021 19:51:58
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:56:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:19
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '4-5 times per week'	Breanna Galibert (b) (4)	03 Feb 2021 19:51:58
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:56:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:19
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	03 Feb 2021 19:51:58
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:56:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:19
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	03 Feb 2021 19:51:58
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:56:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:19
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'un Oct 2020'	Breanna Galibert (b) (4)	03 Feb 2021 19:51:58
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:56:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:19
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	03 Feb 2021 19:51:58
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:56:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:19
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Feb 2021 19:51:58
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:19
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '04 Dec 2020'	Breanna Galibert (b) (4)	03 Feb 2021 19:51:58
	(b) (4)	



US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:56:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:19
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Feb 2021 19:51:58
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:56:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:19
User entered empty.	System	03 Feb 2021 19:51:58

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:56:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:19
User entered empty.	System	03 Feb 2021 19:51:58

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:56:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:19
User entered empty.	System	03 Feb 2021 19:51:58

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:56:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:20
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:28:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:28:55
Data point term sent to Coder	System	20 Feb 2021 19:41:51
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:41:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Feb 2021 13:29:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Feb 2021 13:29:41
Data point term sent to Coder	System	03 Feb 2021 19:52:59
User entered 'vitamin c'	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:52:48

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:56:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Feb 2021 19:52:48
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:56:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'prostate cancer and multiple myeloma'	Breanna Galibert (b) (4)	03 Feb 2021 19:52:48
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:56:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '1000'	Breanna Galibert (b) (4)	03 Feb 2021 19:52:48
	(b) (4)	



US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:56:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	Breanna Galibert (b) (4)	03 Feb 2021 19:53:33
	(b) (4)	
User entered 'ug (ug)'	Breanna Galibert (b) (4)	03 Feb 2021 19:52:48
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:56:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	03 Feb 2021 19:52:48
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:56:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'other (OTHER)'	Breanna Galibert (b) (4)	03 Feb 2021 19:52:48
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:56:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '4-5 times per week'	Breanna Galibert (b) (4)	03 Feb 2021 19:52:48
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:56:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	03 Feb 2021 19:52:48
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:56:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	03 Feb 2021 19:52:48
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:56:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'un Oct 2020'	Breanna Galibert (b) (4)	03 Feb 2021 19:52:48
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:56:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	03 Feb 2021 19:52:48
	(b) (4)	



US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:56:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Feb 2021 19:52:48
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '04 Dec 2020'	Breanna Galibert (b) (4)	03 Feb 2021 19:52:48
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:56:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Feb 2021 19:52:48
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:56:12**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:20
User entered empty.	System	03 Feb 2021 19:52:48

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:56:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:20
User entered empty.	System	03 Feb 2021 19:52:48

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:56:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:20
User entered empty.	System	03 Feb 2021 19:52:48

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:56:12

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:27:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:27:59
Data point term sent to Coder	System	20 Feb 2021 19:41:51
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:41:45
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Feb 2021 11:27:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Feb 2021 11:27:07
Data point term sent to Coder	System	03 Feb 2021 19:53:59
User entered 'fish oil'	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:53:24

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:56:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Feb 2021 19:53:24
	(b) (4)	



US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:56:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'prostate cancer and multiple myeloma'	Breanna Galibert (b) (4)	03 Feb 2021 19:53:24
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:56:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '1000'	Breanna Galibert (b) (4)	03 Feb 2021 19:53:24
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:56:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'mg (mg)'	Breanna Galibert (b) (4)	03 Feb 2021 19:53:24
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:56:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	03 Feb 2021 19:53:24
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:56:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'other (OTHER)'	Breanna Galibert (b) (4)	03 Feb 2021 19:53:24
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:56:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '4-5 times per week'	Breanna Galibert (b) (4)	03 Feb 2021 19:53:24
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:56:12**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	03 Feb 2021 19:53:24
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:56:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	03 Feb 2021 19:53:24
	(b) (4)	



**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'un Oct 2020'	Breanna Galibert (b) (4)	03 Feb 2021 19:53:24
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:56:12**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	03 Feb 2021 19:53:24
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:56:12**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	03 Feb 2021 19:53:24
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	03 Feb 2021 19:53:24
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:56:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Feb 2021 19:53:24
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:56:12**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 19:53:24

US3812098

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:56:12**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 19:53:24

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:56:12**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 19:53:24



US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:56:12

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Feb 2021 20:28:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Feb 2021 20:28:54
Data point term sent to Coder	System	20 Feb 2021 19:41:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 11:45:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 11:45:44
Data point term sent to Coder	System	03 Feb 2021 19:55:00
User entered 'tramadol'	Breanna Galibert (b) (4)	03 Feb 2021 19:54:20

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:56:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Feb 2021 19:54:20
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:56:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'multiple myeloma'	Breanna Galibert (b) (4)	03 Feb 2021 19:54:20
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:56:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '100'	Breanna Galibert (b) (4)	03 Feb 2021 19:54:20
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:56:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'mg (mg)'	Breanna Galibert (b) (4)	03 Feb 2021 19:54:20
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:56:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	03 Feb 2021 19:54:20
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:56:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'other (OTHER)'	Breanna Galibert (b) (4)	03 Feb 2021 19:54:20
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:56:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'every 6 hours as needed'	Breanna Galibert (b) (4)	03 Feb 2021 19:54:20
	(b) (4)	



**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:56:12**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	03 Feb 2021 19:54:20
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:56:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	03 Feb 2021 19:54:20
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:56:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '02 Dec 2020'	Breanna Galibert (b) (4)	03 Feb 2021 19:54:20
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:56:12**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	03 Feb 2021 19:54:20
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:56:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	03 Feb 2021 19:54:20
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	03 Feb 2021 19:54:20
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:56:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Feb 2021 19:54:20
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:56:12**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 19:54:20



**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:56:12**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 19:54:20

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:56:12**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 19:54:20

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:56:12

Name of Medication

Audit	User	Time (GMT)
User closed query ""Per MM, please confirm if this is prohibited medication per protocol section 6.4.3 ""Concomitant Medications and Vaccines that May Lead to the Elimination of a Participant from Per-Protocol Analyses"" (Site from DM).	(b) (4), (b) (6)	27 Apr 2021 07:26:38
Query ""Per MM, please confirm if this is prohibited medication per protocol section 6.4.3 ""Concomitant Medications and Vaccines that May Lead to the Elimination of a Participant from Per-Protocol Analyses"" answered with 'medication was given after study enrollment and after first two IP vaccinations. Subject is now being followed for safety when unblinded subject was given mRNA during vaccine one and vaccine two visits. ' (Site from DM).	Angie Kean (b) (4)	07 Apr 2021 16:42:06
User opened query ""Per MM, please confirm if this is prohibited medication per protocol section 6.4.3 ""Concomitant Medications and Vaccines that May Lead to the Elimination of a Participant from Per-Protocol Analyses"" (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 10:35:06
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ANTINEOPLASTIC AGENTS, ATC: OTHER ANTINEOPLASTIC AGENTS, ATC: OTHER ANTINEOPLASTIC AGENTS, PRODUCT: BORTEZOMIB, PRODUCTSYNONYM: VELCADE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Feb 2021 20:13:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Feb 2021 20:13:13
Data point term sent to Coder	System	20 Feb 2021 19:41:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:56:12

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ANTINEOPLASTIC AGENTS, ATC: OTHER ANTINEOPLASTIC AGENTS, ATC: OTHER ANTINEOPLASTIC AGENTS, PRODUCT: BORTEZOMIB, PRODUCTSYNONYM: VELCADE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Feb 2021 19:56:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Feb 2021 19:56:28
Data point term sent to Coder	System	03 Feb 2021 19:56:01
User entered 'velcade'	Breanna Galibert (b) (4)	03 Feb 2021 19:55:15

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:56:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Feb 2021 19:55:15
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:56:12**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'multiple myeloma'	Breanna Galibert (b) (4)	03 Feb 2021 19:55:15
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:56:12**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'unk'	Breanna Galibert (b) (4)	03 Feb 2021 19:55:15
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:56:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Other (OTHER)'	Breanna Galibert (b) (4)	03 Feb 2021 19:55:15
	(b) (4)	



US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:56:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'unk'	Breanna Galibert (b) (4)	03 Feb 2021 19:55:15
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:56:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'every week (QS)'	Breanna Galibert (b) (4)	03 Feb 2021 19:55:15
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:56:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	03 Feb 2021 19:55:15
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:56:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Subcutaneous (SUBCUTANEOUS)'	Breanna Galibert (b) (4)	03 Feb 2021 19:55:15
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:56:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	03 Feb 2021 19:55:15
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:56:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '08 Dec 2020'	Breanna Galibert (b) (4)	03 Feb 2021 19:55:15
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:56:12**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	03 Feb 2021 19:55:15
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:56:12**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	03 Feb 2021 19:55:15
	(b) (4)	



US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	03 Feb 2021 19:55:15
	(b) (4)	

US3812098

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:56:12**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Feb 2021 19:55:15
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:56:12**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 19:55:15

US3812098

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:56:12**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 19:55:15

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:56:12**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	03 Feb 2021 19:55:15

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:56:12

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with CM# 9 (08Dec2020 - ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 18:55:51
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with CM# 9 (08Dec2020 - ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' answered with 'updated' (Site from DM).	Angie Kean (b) (4)	07 Apr 2021 16:46:51
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with CM# 9 (08Dec2020 - ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 21:41:28
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: IMMUNOSUPPRESSANTS, ATC: OTHER IMMUNOSUPPRESSANTS, PRODUCT: LENALIDOMIDE, PRODUCTSYNONYM: REVLIMID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Feb 2021 20:13:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Feb 2021 20:13:15
Data point term sent to Coder	System	20 Feb 2021 19:41:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: IMMUNOSUPPRESSANTS, ATC: OTHER IMMUNOSUPPRESSANTS, PRODUCT: LENALIDOMIDE, PRODUCTSYNONYM: REVLIMID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 11:29:43

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:56:12

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	04 Feb 2021 11:29:43
User: (b) (6) - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	03 Feb 2021 19:57:02
User entered 'revlimid'	Breanna Galibert (b) (4)	03 Feb 2021 19:56:09
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:56:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Feb 2021 19:56:09
	(b) (4)	



US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:56:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'multiple myeloma'	Breanna Galibert (b) (4)	03 Feb 2021 19:56:09
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:56:12**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '25'	Breanna Galibert (b) (4)	03 Feb 2021 19:56:09
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:56:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'mg (mg)'	Breanna Galibert (b) (4)	03 Feb 2021 19:56:09
	(b) (4)	

US3812098

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:56:12**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	03 Feb 2021 19:56:09
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:56:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'other (OTHER)'	Breanna Galibert (b) (4)	03 Feb 2021 19:56:09
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:56:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'daily days 1-14 every 21 days'	Breanna Galibert (b) (4)	03 Feb 2021 19:56:09
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:56:12**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	03 Feb 2021 19:56:09
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:56:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	03 Feb 2021 19:56:09
	(b) (4)	



US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:56:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '08 Dec 2020'	Breanna Galibert (b) (4)	03 Feb 2021 19:56:09
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:56:12

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	03 Feb 2021 19:56:09
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:56:12**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	03 Feb 2021 19:56:09
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	03 Feb 2021 19:56:09
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:56:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Feb 2021 19:56:09
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:56:12**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 19:56:09

US3812098

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:56:12**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 19:56:09

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:56:12**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 19:56:09



US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:56:12

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with CM# 15 (08Dec2020 - ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 18:57:50
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with CM# 15 (08Dec2020 - ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' answered with 'updated. duplicate entry, log line #15 inactivated. ' (Site from DM).	Angie Kean (b) (4) (b) (4)	07 Apr 2021 16:43:55
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with CM# 15 (08Dec2020 - ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 21:42:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:28:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:28:55
Data point term sent to Coder	System	20 Feb 2021 19:41:52
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:41:45

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:56:12

[Name of Medication](#)

Audit	User	Time (GMT)
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: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Feb 2021 20:45:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Feb 2021 20:45:57
Data point term sent to Coder	System	03 Feb 2021 19:57:02
User entered 'pepcid'	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:56:32

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:56:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Feb 2021 19:56:32
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:56:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'multiple myeloma'	Breanna Galibert (b) (4)	03 Feb 2021 19:56:32
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:56:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '20'	Breanna Galibert (b) (4)	03 Feb 2021 19:56:32
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:56:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'mg (mg)'	Breanna Galibert (b) (4)	03 Feb 2021 19:56:32
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:56:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	03 Feb 2021 19:56:32
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:56:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'once daily (QD)'	Breanna Galibert (b) (4)	03 Feb 2021 19:56:32
	(b) (4)	



US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:56:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	03 Feb 2021 19:56:32
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:56:12**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	03 Feb 2021 19:56:32
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:56:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	03 Feb 2021 19:56:32
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '08 Dec 2020'	Breanna Galibert (b) (4)	03 Feb 2021 19:56:32
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:56:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	03 Feb 2021 19:56:32
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:56:12**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	03 Feb 2021 19:56:32
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	03 Feb 2021 19:56:32
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:56:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Feb 2021 19:56:32
	(b) (4)	



**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:56:12**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 19:56:32

US3812098

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:56:12**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 19:56:32

US3812098

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:56:12**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Feb 2021 19:56:32

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:56:12

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: OTHER DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, PRODUCT: DENOSUMAB, PRODUCTSYNONYM: XGEVA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:15
Data point term sent to Coder	System	20 Feb 2021 19:41:55
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:41:45
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: OTHER DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, PRODUCT: DENOSUMAB, PRODUCTSYNONYM: XGEVA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 19:58:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 19:58:27
Data point term sent to Coder	System	03 Feb 2021 19:58:03
User entered 'xgeva'	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:57:10

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:56:12**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Feb 2021 19:57:10
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:56:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'multiple myeloma'	Breanna Galibert (b) (4)	03 Feb 2021 19:57:10
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:56:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '120'	Breanna Galibert (b) (4)	03 Feb 2021 19:57:10
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:56:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'mg (mg)'	Breanna Galibert (b) (4)	03 Feb 2021 19:57:10
	(b) (4)	



US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:56:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	03 Feb 2021 19:57:10
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:56:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'every month (QM)'	Breanna Galibert (b) (4)	03 Feb 2021 19:57:10
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:56:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	03 Feb 2021 19:57:10
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:56:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Subcutaneous (SUBCUTANEOUS)'	Breanna Galibert (b) (4)	03 Feb 2021 19:57:10
	(b) (4)	

US3812098

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:56:12**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	03 Feb 2021 19:57:10
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '08 Dec 2020'	Breanna Galibert (b) (4)	03 Feb 2021 19:57:10
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:56:12**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	03 Feb 2021 19:57:10
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:56:12**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	03 Feb 2021 19:57:10
	(b) (4)	



US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	03 Feb 2021 19:57:10
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:56:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Feb 2021 19:57:10
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:56:12**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 19:57:10

US3812098

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:56:12**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 19:57:10

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:56:12**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '802 (802)'	System	03 Feb 2021 19:57:10

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:56:12

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE, PRODUCTSYNONYM: LIDODERM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 07:34:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 07:34:39
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:27:46
Data point term sent to Coder	System	07 Apr 2021 16:37:51
Coding entries removed.	Angie Kean (b) (4) (b) (4)	07 Apr 2021 16:37:51
Signature has been broken.	Angie Kean (b) (4) (b) (4)	07 Apr 2021 16:37:51
User entered 'LIDODERM 5%' reason for change: New Information	Angie Kean (b) (4) (b) (4)	07 Apr 2021 16:37:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE, PRODUCTSYNONYM: LIDODERM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:00
Data point term sent to Coder	System	20 Feb 2021 19:41:55
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:41:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE, PRODUCTSYNONYM: LIDODERM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 09:37:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 09:37:45
Data point term sent to Coder	System	03 Feb 2021 19:58:04

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:56:12

Name of Medication

Audit	User	Time (GMT)
User entered 'lidoderm'	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:57:58

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:56:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Feb 2021 19:57:58
	(b) (4)	



US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:56:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'multiple myeloma'	Breanna Galibert (b) (4)	03 Feb 2021 19:57:58
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:56:12

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Note, 5% is a concentration, please update medication name to include this concentration and consider recording the number of applications instead in the dose and dose unit fields (e.g. dose=1; unit=application/patch). Review and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 18:42:43
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Query 'Per DM CLR: Note, 5% is a concentration, please update medication name to include this concentration and consider recording the number of applications instead in the dose and dose unit fields (e.g. dose=1; unit=application/patch). Review and amend as appropriate. ' answered with 'updated' (Site from DM).	Angie Kean (b) (4)	07 Apr 2021 16:37:55
Signature has been broken.	Angie Kean (b) (4)	07 Apr 2021 16:37:51
User entered '1' reason for change: New Information	Angie Kean (b) (4)	07 Apr 2021 16:37:51
User opened query 'Per DM CLR: Note, 5% is a concentration, please update medication name to include this concentration and consider recording the number of applications instead in the dose and dose unit fields (e.g. dose=1; unit=application/patch). Review and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 21:43:02
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '5'	Breanna Galibert (b) (4)	03 Feb 2021 19:57:58

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:56:12**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Other (OTHER)'	Breanna Galibert (b) (4)	03 Feb 2021 19:57:58
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:56:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
	(b) (4)	
Signature has been broken.	Angie Kean (b) (4)	07 Apr 2021 16:37:51
	(b) (4)	
User entered 'application' reason for change: New Information	Angie Kean (b) (4)	07 Apr 2021 16:37:51
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '%'	Breanna Galibert (b) (4)	03 Feb 2021 19:57:58
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:56:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'other (OTHER)'	Breanna Galibert (b) (4)	03 Feb 2021 19:57:58
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:56:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'daily as needed'	Breanna Galibert (b) (4)	03 Feb 2021 19:57:58
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:56:12**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Transdermal (TRANSDERMAL)'	Breanna Galibert (b) (4)	03 Feb 2021 19:57:58
	(b) (4)	

US3812098

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:56:12**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	03 Feb 2021 19:57:58
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:56:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '22 Dec 2020'	Breanna Galibert (b) (4)	03 Feb 2021 19:57:58
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:56:12**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	03 Feb 2021 19:57:58
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:56:12**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	03 Feb 2021 19:57:58
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	03 Feb 2021 19:57:58
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:56:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Feb 2021 19:57:58
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:56:12**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 19:57:58

US3812098

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:56:12**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 19:57:58

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:56:12**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 19:57:58



US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:56:12

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM OXALATE, PRODUCTSYNONYM: LEXAPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:28:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:28:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM OXALATE, PRODUCTSYNONYM: LEXAPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 20:13:14
Data point term sent to Coder	System	20 Feb 2021 19:41:55
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:41:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM OXALATE, PRODUCTSYNONYM: LEXAPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 11:13:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 11:13:53
Data point term sent to Coder	System	03 Feb 2021 19:59:04
User entered 'lexapro'	Breanna Galibert (b) (4) (b) (4)	03 Feb 2021 19:58:29

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:56:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Feb 2021 19:58:29
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:56:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'worsening anxiety'	Breanna Galibert (b) (4)	03 Feb 2021 19:58:29
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:56:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '10'	Breanna Galibert (b) (4)	03 Feb 2021 19:58:29
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:56:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'mg (mg)'	Breanna Galibert (b) (4)	03 Feb 2021 19:58:29
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:56:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	03 Feb 2021 19:58:29
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:56:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'once daily (QD)'	Breanna Galibert (b) (4)	03 Feb 2021 19:58:29
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:56:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	03 Feb 2021 19:58:29
	(b) (4)	



US3812098

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:56:12**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	03 Feb 2021 19:58:29
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:56:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	03 Feb 2021 19:58:29
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:56:12**

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

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '05 Jan 2021'	Breanna Galibert (b) (4)	03 Feb 2021 19:58:29
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:56:12**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	03 Feb 2021 19:58:29
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:56:12**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	03 Feb 2021 19:58:29
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:56:12

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

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	03 Feb 2021 19:58:29
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:56:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Feb 2021 19:58:29
	(b) (4)	

**US3812098**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:56:12**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 19:58:29



US3812098

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:56:12**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 19:58:29

US3812098

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:56:12**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Feb 2021 19:58:29

US3812098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:56:12

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:01:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:12
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	14 Oct 2020 18:29:36
User entered 'No (N)'	Karen Knapp (b) (4)	03 Sep 2020 14:21:46

US3812098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:56:12

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:23:53
User entered '02 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 18:30:29

US3812098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:56:12

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:23:53
User entered 'Biopsy of Prostate'	(b) (4), (b) (6)	14 Oct 2020 18:30:29

US3812098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:56:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:23:53
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	14 Oct 2020 18:30:29

US3812098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:56:12

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:23:53
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:30:29

US3812098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:56:12

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:23:53
User entered '15 Oct 2020'	Anya Penly (b) (4) (b) (4)	21 Oct 2020 14:39:23



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:56:12

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:23:53
User entered 'left cataract removal'	Anya Penly (b) (4) (b) (4)	21 Oct 2020 14:39:23

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:56:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:23:53
User entered 'Adverse Event (AE)'	Anya Penly (b) (4) (b) (4)	21 Oct 2020 14:39:23

US3812098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:56:12

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:23:53
User entered empty.	Anya Penly (b) (4) (b) (4)	21 Oct 2020 14:39:23

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:56:12

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:31
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:57
User entered '17 Nov 2020'	lauren clement (b) (4)	17 Mar 2021 17:30:42

US3812098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:56:12

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:31
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:57
User entered 'CT PET SCAN'	lauren clement (b) (4)	17 Mar 2021 17:30:42

US3812098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:56:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:31
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:57
User entered 'Adverse Event (AE)'	lauren clement (b) (4)	17 Mar 2021 17:30:42

US3812098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:56:12

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:31
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:57
User entered empty.	lauren clement (b) (4)	17 Mar 2021 17:30:42

US3812098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:56:12

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:34
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
User entered '2 Dec 2020'	Angie Kean (b) (4)	06 Apr 2021 21:53:34



US3812098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:56:12

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:34
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
User entered 'peripheral blood smear'	Angie Kean (b) (4)	06 Apr 2021 21:53:34

US3812098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:56:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:34
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
User entered 'Adverse Event (AE)'	Angie Kean (b) (4)	06 Apr 2021 21:53:34

US3812098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:56:12

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:34
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
User entered empty.	Angie Kean (b) (4)	06 Apr 2021 21:53:34

US3812098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:56:12

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:31
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
User entered '02 Dec 2020'	Angie Kean (b) (4)	06 Apr 2021 21:53:59

US3812098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:56:12

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:31
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
User entered 'bone marrow aspirate'	Angie Kean (b) (4)	06 Apr 2021 21:53:59

US3812098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:56:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:31
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
User entered 'Adverse Event (AE)'	Angie Kean (b) (4)	06 Apr 2021 21:53:59

US3812098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:56:12

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:31
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
User entered empty.	Angie Kean (b) (4)	06 Apr 2021 21:53:59

US3812098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:56:12

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
User entered '31 Mar 2021'	Angie Kean (b) (4)	06 Apr 2021 21:54:24
	(b) (4)	



US3812098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:56:12

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
User entered 'Stem cell transplant'	Angie Kean (b) (4)	06 Apr 2021 21:54:24
	(b) (4)	

US3812098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:56:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
User entered 'Adverse Event (AE)'	Angie Kean (b) (4)	06 Apr 2021 21:54:24
	(b) (4)	

US3812098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:56:12

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
User entered empty.	Angie Kean (b) (4)	06 Apr 2021 21:54:24
	(b) (4)	

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered	System	15 Oct 2020 12:46:37
'USA-US111-2020-MRNA-1273-P301000005'		

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Yes (Y)'	System	15 Oct 2020 12:46:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:54:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:27:20
Un-reviewed for Safety.	System	05 Nov 2020 22:20:40
DataPoint Un-verified.	System	05 Nov 2020 22:20:40
User entered 'No (N)'	System	05 Nov 2020 22:20:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered 'Yes (Y)'	System	19 Oct 2020 16:58:06
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:58:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 16:58:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Yes (Y)'	System	15 Oct 2020 12:46:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37



**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:55:04
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:27:20
Un-reviewed for Safety.	System	05 Nov 2020 22:20:40
DataPoint Un-verified.	System	05 Nov 2020 22:20:40
User entered 'Yes (Y)'	System	05 Nov 2020 22:20:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered 'No (N)'	System	19 Oct 2020 16:58:06
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:58:06
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 16:58:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered 'lauren'	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Larkin'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered 'clement'	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Wadsworth'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered '711 Old Ballas Rd Suite 105'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'St Louis'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered 'MO'	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered empty.	System	19 Oct 2020 16:58:06
User entered 'MO'	(b) (4), (b) (6)	19 Oct 2020 16:57:34



US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered '63141'	System	15 Oct 2020 12:46:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered 'US'	System	15 Oct 2020 12:47:06

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	08 Apr 2021 14:38:51
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '5'	System	16 Feb 2021 18:44:26
User entered '4'	System	16 Nov 2020 14:29:53
User entered '3'	System	06 Nov 2020 20:27:39
User entered '2'	System	23 Oct 2020 00:21:26
User entered '1'	System	15 Oct 2020 12:47:06

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'USA-US111-2020-MRNA-1273-P301000005'	System	15 Oct 2020 12:46:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Yes (Y)'	System	15 Oct 2020 12:46:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:54:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:27:20
Un-reviewed for Safety.	System	05 Nov 2020 22:20:40
DataPoint Un-verified.	System	05 Nov 2020 22:20:40
User entered 'No (N)'	System	05 Nov 2020 22:20:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered 'Yes (Y)'	System	19 Oct 2020 16:58:06
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:58:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 16:58:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Yes (Y)'	System	15 Oct 2020 12:46:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37



**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:55:04
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:27:20
Un-reviewed for Safety.	System	05 Nov 2020 22:20:40
DataPoint Un-verified.	System	05 Nov 2020 22:20:40
User entered 'Yes (Y)'	System	05 Nov 2020 22:20:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered 'No (N)'	System	19 Oct 2020 16:58:06
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:58:06
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 16:58:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered 'lauren'	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Larkin'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered 'clement'	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Wadsworth'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered '711 Old Ballas Rd Suite 105'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'St Louis'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered 'MO'	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered empty.	System	19 Oct 2020 16:58:06
User entered 'MO'	(b) (4), (b) (6)	19 Oct 2020 16:57:34



US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered '63141'	System	15 Oct 2020 12:46:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered 'US'	System	15 Oct 2020 12:47:06

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	08 Apr 2021 14:38:51
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '5'	System	16 Feb 2021 18:44:26
User entered '4'	System	16 Nov 2020 14:29:53
User entered '3'	System	06 Nov 2020 20:27:39
User entered '2'	System	23 Oct 2020 00:21:26
User entered '1'	System	15 Oct 2020 12:47:06

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:56:12**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:39
User entered '15/Oct/2020 12:47'	System	15 Oct 2020 12:47:06

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:56:12

**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.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered 'I'	(b) (4), (b) (6)	15 Oct 2020 12:47:06

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'USA-US111-2020-MRNA-1273-P301000005'	System	15 Oct 2020 12:46:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Yes (Y)'	System	15 Oct 2020 12:46:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37



US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:54:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:27:20
Un-reviewed for Safety.	System	05 Nov 2020 22:20:40
DataPoint Un-verified.	System	05 Nov 2020 22:20:40
User entered 'No (N)'	System	05 Nov 2020 22:20:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered 'Yes (Y)'	System	19 Oct 2020 16:58:06
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:58:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 16:58:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Yes (Y)'	System	15 Oct 2020 12:46:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:55:04
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:27:20
Un-reviewed for Safety.	System	05 Nov 2020 22:20:40
DataPoint Un-verified.	System	05 Nov 2020 22:20:40
User entered 'Yes (Y)'	System	05 Nov 2020 22:20:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered 'No (N)'	System	19 Oct 2020 16:58:06
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:58:06
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 16:58:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered 'lauren'	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Larkin'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered 'clement'	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Wadsworth'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered '711 Old Ballas Rd Suite 105'	System	15 Oct 2020 12:46:37



US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'St Louis'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered 'MO'	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered empty.	System	19 Oct 2020 16:58:06
User entered 'MO'	(b) (4), (b) (6)	19 Oct 2020 16:57:34

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered '63141'	System	15 Oct 2020 12:46:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered 'US'	System	15 Oct 2020 12:47:06

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	08 Apr 2021 14:38:51
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '5'	System	16 Feb 2021 18:44:26
User entered '4'	System	16 Nov 2020 14:29:53
User entered '3'	System	06 Nov 2020 20:27:39
User entered '2'	System	23 Oct 2020 00:21:26
User entered '1'	System	15 Oct 2020 12:47:06

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:56:12**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:39
User entered '22/Oct/2020 20:21'	System	23 Oct 2020 00:21:26

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:56:12

**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.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:27:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
User entered 'I'	(b) (4), (b) (6)	23 Oct 2020 00:21:26

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'USA-US111-2020-MRNA-1273-P301000005'	System	15 Oct 2020 12:46:37



**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Yes (Y)'	System	15 Oct 2020 12:46:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:54:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:27:20
Un-reviewed for Safety.	System	05 Nov 2020 22:20:40
DataPoint Un-verified.	System	05 Nov 2020 22:20:40
User entered 'No (N)'	System	05 Nov 2020 22:20:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered 'Yes (Y)'	System	19 Oct 2020 16:58:06
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:58:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 16:58:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Yes (Y)'	System	15 Oct 2020 12:46:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:55:04
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:27:20
Un-reviewed for Safety.	System	05 Nov 2020 22:20:40
DataPoint Un-verified.	System	05 Nov 2020 22:20:40
User entered 'Yes (Y)'	System	05 Nov 2020 22:20:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered 'No (N)'	System	19 Oct 2020 16:58:06
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:58:06
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 16:58:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered 'lauren'	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Larkin'	System	15 Oct 2020 12:46:37



US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered 'clement'	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Wadsworth'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered '711 Old Ballas Rd Suite 105'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'St Louis'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered 'MO'	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered empty.	System	19 Oct 2020 16:58:06
User entered 'MO'	(b) (4), (b) (6)	19 Oct 2020 16:57:34

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered '63141'	System	15 Oct 2020 12:46:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered 'US'	System	15 Oct 2020 12:47:06

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	08 Apr 2021 14:38:51
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '5'	System	16 Feb 2021 18:44:26
User entered '4'	System	16 Nov 2020 14:29:53
User entered '3'	System	06 Nov 2020 20:27:39
User entered '2'	System	23 Oct 2020 00:21:26
User entered '1'	System	15 Oct 2020 12:47:06

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 09:56:12**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '06/Nov/2020 20:27'	(b) (4) System	06 Nov 2020 20:27:39



US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:56:12

**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.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:39
User entered 'I'	(b) (4), (b) (6)	06 Nov 2020 20:27:39

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered	System	15 Oct 2020 12:46:37
'USA-US111-2020-MRNA-1273-P301000005'		

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Yes (Y)'	System	15 Oct 2020 12:46:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:54:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:27:20
Un-reviewed for Safety.	System	05 Nov 2020 22:20:40
DataPoint Un-verified.	System	05 Nov 2020 22:20:40
User entered 'No (N)'	System	05 Nov 2020 22:20:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered 'Yes (Y)'	System	19 Oct 2020 16:58:06
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:58:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 16:58:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Yes (Y)'	System	15 Oct 2020 12:46:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37



US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:55:04
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:27:20
Un-reviewed for Safety.	System	05 Nov 2020 22:20:40
DataPoint Un-verified.	System	05 Nov 2020 22:20:40
User entered 'Yes (Y)'	System	05 Nov 2020 22:20:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered 'No (N)'	System	19 Oct 2020 16:58:06
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:58:06
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 16:58:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered 'lauren'	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Larkin'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered 'clement'	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Wadsworth'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered '711 Old Ballas Rd Suite 105'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'St Louis'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered 'MO'	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered empty.	System	19 Oct 2020 16:58:06
User entered 'MO'	(b) (4), (b) (6)	19 Oct 2020 16:57:34

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered '63141'	System	15 Oct 2020 12:46:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered 'US'	System	15 Oct 2020 12:47:06



US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	08 Apr 2021 14:38:51
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '5'	System	16 Feb 2021 18:44:26
User entered '4'	System	16 Nov 2020 14:29:53
User entered '3'	System	06 Nov 2020 20:27:39
User entered '2'	System	23 Oct 2020 00:21:26
User entered '1'	System	15 Oct 2020 12:47:06

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 09:56:12**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:00:21
User entered '16/Nov/2020 09:29'	System	16 Nov 2020 14:29:53

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:56:12

**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.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 18:44:07
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:00:20
User entered 'I'	(b) (4), (b) (6)	16 Nov 2020 14:29:53

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'USA-US111-2020-MRNA-1273-P301000005'	System	15 Oct 2020 12:46:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Yes (Y)'	System	15 Oct 2020 12:46:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:54:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:27:20
Un-reviewed for Safety.	System	05 Nov 2020 22:20:40
DataPoint Un-verified.	System	05 Nov 2020 22:20:40
User entered 'No (N)'	System	05 Nov 2020 22:20:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered 'Yes (Y)'	System	19 Oct 2020 16:58:06
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:58:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 16:58:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Yes (Y)'	System	15 Oct 2020 12:46:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37



**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:55:04
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:27:20
Un-reviewed for Safety.	System	05 Nov 2020 22:20:40
DataPoint Un-verified.	System	05 Nov 2020 22:20:40
User entered 'Yes (Y)'	System	05 Nov 2020 22:20:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered 'No (N)'	System	19 Oct 2020 16:58:06
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:58:06
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 16:58:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered 'lauren'	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Larkin'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered 'clement'	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Wadsworth'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered '711 Old Ballas Rd Suite 105'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'St Louis'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered 'MO'	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered empty.	System	19 Oct 2020 16:58:06
User entered 'MO'	(b) (4), (b) (6)	19 Oct 2020 16:57:34



US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered '63141'	System	15 Oct 2020 12:46:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered 'US'	System	15 Oct 2020 12:47:06

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	08 Apr 2021 14:38:51
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '5'	System	16 Feb 2021 18:44:26
User entered '4'	System	16 Nov 2020 14:29:53
User entered '3'	System	06 Nov 2020 20:27:39
User entered '2'	System	23 Oct 2020 00:21:26
User entered '1'	System	15 Oct 2020 12:47:06

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (5)**

**Generated On: 10 Jun 2021 09:56:12**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '16/Feb/2021 12:44'	(b) (4) System	16 Feb 2021 18:44:26

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:56:12

**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.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'I'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:44:26

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered	System	15 Oct 2020 12:46:37
'USA-US111-2020-MRNA-1273-P301000005'		

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Yes (Y)'	System	15 Oct 2020 12:46:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37



US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:54:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:27:20
Un-reviewed for Safety.	System	05 Nov 2020 22:20:40
DataPoint Un-verified.	System	05 Nov 2020 22:20:40
User entered 'No (N)'	System	05 Nov 2020 22:20:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered 'Yes (Y)'	System	19 Oct 2020 16:58:06
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:58:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 16:58:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Yes (Y)'	System	15 Oct 2020 12:46:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:55:04
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:27:20
Un-reviewed for Safety.	System	05 Nov 2020 22:20:40
DataPoint Un-verified.	System	05 Nov 2020 22:20:40
User entered 'Yes (Y)'	System	05 Nov 2020 22:20:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered 'No (N)'	System	19 Oct 2020 16:58:06
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:58:06
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 16:58:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered 'lauren'	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Larkin'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered 'clement'	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Wadsworth'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered '711 Old Ballas Rd Suite 105'	System	15 Oct 2020 12:46:37



US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'St Louis'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered 'MO'	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered empty.	System	19 Oct 2020 16:58:06
User entered 'MO'	(b) (4), (b) (6)	19 Oct 2020 16:57:34

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered '63141'	System	15 Oct 2020 12:46:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered 'US'	System	15 Oct 2020 12:47:06

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	08 Apr 2021 14:38:51
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '5'	System	16 Feb 2021 18:44:26
User entered '4'	System	16 Nov 2020 14:29:53
User entered '3'	System	06 Nov 2020 20:27:39
User entered '2'	System	23 Oct 2020 00:21:26
User entered '1'	System	15 Oct 2020 12:47:06

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (6)**

**Generated On: 10 Jun 2021 09:56:12**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 16:26:13
User entered '08/Apr/2021 07:38'	System	08 Apr 2021 14:38:51

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:56:12

**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.	Lyly Dang (b) (4)	08 Apr 2021 16:26:13
User entered 'I'	(b) (4), (b) (6)	08 Apr 2021 14:38:51

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'USA-US111-2020-MRNA-1273-P301000020'	System	09 Dec 2020 20:25:37



US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'Yes (Y)'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'No (N)'	System	09 Dec 2020 20:25:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'No (N)'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'No (N)'	System	09 Dec 2020 20:25:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'No (N)'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'No (N)'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'Yes (Y)'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered 'lauren'	System	07 Apr 2021 15:21:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'Larkin'	System	09 Dec 2020 20:25:37



US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered 'clement'	System	07 Apr 2021 15:21:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'Wadsworth'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered '711 Old Ballas Rd Suite 105'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'St Louis'	System	09 Dec 2020 20:25:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
User entered 'MO'	System	07 Apr 2021 15:21:31

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered '63141'	System	09 Dec 2020 20:25:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 19:46:22
User entered 'US'	System	09 Dec 2020 20:26:57

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 14:39:32
User entered '4'	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '3'	System	09 Feb 2021 18:38:16
User entered '2'	System	07 Jan 2021 19:46:38
User entered '1'	System	09 Dec 2020 20:26:57

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'USA-US111-2020-MRNA-1273-P301000020'	System	09 Dec 2020 20:25:37



US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'Yes (Y)'	System	09 Dec 2020 20:25:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'No (N)'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'No (N)'	System	09 Dec 2020 20:25:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'No (N)'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'No (N)'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'No (N)'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'Yes (Y)'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered 'lauren'	System	07 Apr 2021 15:21:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'Larkin'	System	09 Dec 2020 20:25:37



US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered 'clement'	System	07 Apr 2021 15:21:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'Wadsworth'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered '711 Old Ballas Rd Suite 105'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'St Louis'	System	09 Dec 2020 20:25:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
User entered 'MO'	System	07 Apr 2021 15:21:31

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered '63141'	System	09 Dec 2020 20:25:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 19:46:22
User entered 'US'	System	09 Dec 2020 20:26:57

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 14:39:32
User entered '4'	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '3'	System	09 Feb 2021 18:38:16
User entered '2'	System	07 Jan 2021 19:46:38
User entered '1'	System	09 Dec 2020 20:26:57

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000020**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:56:12**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '09/Dec/2020 15:26'	(b) (4) System	09 Dec 2020 20:26:57



US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:56:12

**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)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 19:46:22
User entered 'I'	(b) (4), (b) (6)	09 Dec 2020 20:26:57

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'USA-US111-2020-MRNA-1273-P301000020'	System	09 Dec 2020 20:25:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'Yes (Y)'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'No (N)'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'No (N)'	System	09 Dec 2020 20:25:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'No (N)'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'No (N)'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'No (N)'	System	09 Dec 2020 20:25:37



US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'Yes (Y)'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered 'lauren'	System	07 Apr 2021 15:21:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'Larkin'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered 'clement'	System	07 Apr 2021 15:21:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'Wadsworth'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered '711 Old Ballas Rd Suite 105'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'St Louis'	System	09 Dec 2020 20:25:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
User entered 'MO'	System	07 Apr 2021 15:21:31

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered '63141'	System	09 Dec 2020 20:25:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 19:46:22
User entered 'US'	System	09 Dec 2020 20:26:57



US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 14:39:32
User entered '4'	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '3'	System	09 Feb 2021 18:38:16
User entered '2'	System	07 Jan 2021 19:46:38
User entered '1'	System	09 Dec 2020 20:26:57

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000020**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:56:12**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '07/Jan/2021 14:46'	(b) (4) System	07 Jan 2021 19:46:38

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:56:12

**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)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:37:49
User entered '1'	(b) (4), (b) (6)	07 Jan 2021 19:46:38

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'USA-US111-2020-MRNA-1273-P301000020'	System	09 Dec 2020 20:25:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'Yes (Y)'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'No (N)'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'No (N)'	System	09 Dec 2020 20:25:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'No (N)'	System	09 Dec 2020 20:25:37



US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'No (N)'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'No (N)'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'Yes (Y)'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered 'lauren'	System	07 Apr 2021 15:21:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'Larkin'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered 'clement'	System	07 Apr 2021 15:21:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'Wadsworth'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered '711 Old Ballas Rd Suite 105'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'St Louis'	System	09 Dec 2020 20:25:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
User entered 'MO'	System	07 Apr 2021 15:21:31



US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered '63141'	System	09 Dec 2020 20:25:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 19:46:22
User entered 'US'	System	09 Dec 2020 20:26:57

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 14:39:32
User entered '4'	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '3'	System	09 Feb 2021 18:38:16
User entered '2'	System	07 Jan 2021 19:46:38
User entered '1'	System	09 Dec 2020 20:26:57

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000020**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 09:56:12**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered '09/Feb/2021 13:38'	(b) (4) System	09 Feb 2021 18:38:16

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:56:12

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 15:21:16
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
User entered 'I'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:38:16

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'USA-US111-2020-MRNA-1273-P301000020'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'Yes (Y)'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'No (N)'	System	09 Dec 2020 20:25:37



US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'No (N)'	System	09 Dec 2020 20:25:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'No (N)'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'No (N)'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'No (N)'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'Yes (Y)'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered 'lauren'	System	07 Apr 2021 15:21:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'Larkin'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered 'clement'	System	07 Apr 2021 15:21:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'Wadsworth'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered '711 Old Ballas Rd Suite 105'	System	09 Dec 2020 20:25:37



US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'St Louis'	System	09 Dec 2020 20:25:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
User entered 'MO'	System	07 Apr 2021 15:21:31

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered '63141'	System	09 Dec 2020 20:25:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 19:46:22
User entered 'US'	System	09 Dec 2020 20:26:57

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 14:39:32
User entered '4'	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '3'	System	09 Feb 2021 18:38:16
User entered '2'	System	07 Jan 2021 19:46:38
User entered '1'	System	09 Dec 2020 20:26:57

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000020**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 09:56:12**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
User entered '07/Apr/2021 11:21'	System	07 Apr 2021 15:21:31

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:56:12

**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.	Lyly Dang (b) (4) [REDACTED]	08 Apr 2021 01:27:46
User entered 'I'	(b) (4), (b) (6) [REDACTED]	07 Apr 2021 15:21:31

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'USA-US111-2020-MRNA-1273-P301000020'	System	09 Dec 2020 20:25:37



**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'Yes (Y)'	System	09 Dec 2020 20:25:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'No (N)'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'No (N)'	System	09 Dec 2020 20:25:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'No (N)'	System	09 Dec 2020 20:25:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'No (N)'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'No (N)'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'Yes (Y)'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered 'lauren'	System	07 Apr 2021 15:21:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'Larkin'	System	09 Dec 2020 20:25:37



US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered 'clement'	System	07 Apr 2021 15:21:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'Wadsworth'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered '711 Old Ballas Rd Suite 105'	System	09 Dec 2020 20:25:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered 'St Louis'	System	09 Dec 2020 20:25:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
User entered 'MO'	System	07 Apr 2021 15:21:31

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:27:46
Un-reviewed for Safety.	System	07 Apr 2021 15:21:31
DataPoint Un-verified.	System	07 Apr 2021 15:21:31
Signature has been broken.	System	07 Apr 2021 15:21:31
User entered empty.	System	07 Apr 2021 15:21:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 20:26:32
User entered '63141'	System	09 Dec 2020 20:25:37

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:12**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:18:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 19:46:22
User entered 'US'	System	09 Dec 2020 20:26:57

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 14:39:32
User entered '4'	System	07 Apr 2021 15:21:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:41:45
	(b) (4)	
User entered '3'	System	09 Feb 2021 18:38:16
User entered '2'	System	07 Jan 2021 19:46:38
User entered '1'	System	09 Dec 2020 20:26:57

**US3812098**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000020**

**Form: Safety Report Form (5)**

**Generated On: 10 Jun 2021 09:56:12**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 16:26:13
User entered '08/Apr/2021 07:39'	System	08 Apr 2021 14:39:32



US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000020

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:56:12

**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.	Lyly Dang (b) (4)	08 Apr 2021 16:26:13
User entered 'I'	(b) (4), (b) (6)	08 Apr 2021 14:39:32