

US3372228 (Prod: Palm Beach Research Center)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:16:55

All time stamps listed in this document are displayed in GMT

US3372228

**Form: Participant Creation**

**Data signed:** (b) (4) 16 Feb 2021 19:44:39

**Generated On: 09 Jun 2021 17:16:55**

---

[Participant ID](#)

US3372228

---

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

---

---

US3372228

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 03:14:15

Generated On: 09 Jun 2021 17:16:55

---

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

---

US3372228

Folder: Screening

Form: Demographics

Data signed: (b) (4) 16 Feb 2021 23:08:09

Generated On: 09 Jun 2021 17:16:55

Date of Birth (MMM yyyy)	(b) (6) 1965
Age	55
Age Units	YEARS
Age (Derived)	55
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

US3372228

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 16 Feb 2021 23:26:38

Generated On: 09 Jun 2021 17:16:55

Date of Informed Consent (*dd MMM yyyy*) 24 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes   
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify \_\_\_\_\_

Was this participant screened previously? Yes   
No

If Yes, previous participant number \_\_\_\_\_

Enrollment Trigger 1

US3372228

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 17 Feb 2021 00:20:25

Generated On: 09 Jun 2021 17:16:55

---

Did the participant meet all eligibility criteria?

Yes

No

---

US3372228

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 17 Feb 2021 00:52:38

Generated On: 09 Jun 2021 17:16:55

---

Were any significant conditions reported?

Yes

No

---

US3372228

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 16 Mar 2021 19:23:52

Generated On: 09 Jun 2021 17:16:55

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

US3372228

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 16 Mar 2021 19:23:52

Generated On: 09 Jun 2021 17:16:55

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

US3372228

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 16 Mar 2021 19:23:52

Generated On: 09 Jun 2021 17:16:55

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

US3372228

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 16 Mar 2021 19:23:52

Generated On: 09 Jun 2021 17:16:55

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

US3372228

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 16 Mar 2021 19:23:52

Generated On: 09 Jun 2021 17:16:55

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

US3372228

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 16 Mar 2021 19:23:52

Generated On: 09 Jun 2021 17:16:55

Condition	VITAMIN B12 DEFICIENCY
Start date (dd MMM yyyy)	UN AUG 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)	AUG 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3372228

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 16 Mar 2021 19:23:52

Generated On: 09 Jun 2021 17:16:55

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

US3372228

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 16 Mar 2021 19:23:52

Generated On: 09 Jun 2021 17:16:55

Condition	GENERALIZED OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN JUN 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)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3372228

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 16 Mar 2021 19:23:52

Generated On: 09 Jun 2021 17:16:55

Condition	HERNIATED DISC CERVICAL SPINE
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3372228

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 16 Mar 2021 19:23:52

Generated On: 09 Jun 2021 17:16:55

Condition	TONSILLITIS - CHRONIC
Start date (dd MMM yyyy)	UN UNK 1984
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 1986
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1984
Start Year (derived)	1984
Stop Month and Year (derived)	JAN 1986
Stop Year (derived)	1986

US3372228

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 16 Mar 2021 19:23:52

Generated On: 09 Jun 2021 17:16:55

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 1986
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 1986
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1986
Start Year (derived)	1986
Stop Month and Year (derived)	JAN 1986
Stop Year (derived)	1986

US3372228

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 16 Mar 2021 19:23:52

Generated On: 09 Jun 2021 17:16:55

Condition	RIGHT ARMPIT BENIGN LIPOMA
Start date (dd MMM yyyy)	UN UNK 1996
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 1996
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	JAN 1996
Stop Year (derived)	1996

US3372228

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 16 Mar 2021 19:23:52

Generated On: 09 Jun 2021 17:16:55

Condition	RIGHT ARMPIT LIPOMA ENUCLEATION
Start date (dd MMM yyyy)	UN UNK 1996
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 1996
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	JAN 1996
Stop Year (derived)	1996

US3372228

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 16 Mar 2021 19:23:52

Generated On: 09 Jun 2021 17:16:55

Condition	CHOLELITHIASIS
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

US3372228

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 16 Mar 2021 19:23:52

Generated On: 09 Jun 2021 17:16:55

Condition	CHOLECYSTECTOMY
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

US3372228

Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 16 Mar 2021 19:23:52

Generated On: 09 Jun 2021 17:16:55

Condition	HERNIATED DISC THORACIC SPINE
Start date (dd MMM yyyy)	UN UNK 1996
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

US3372228

Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 16 Mar 2021 19:23:52

Generated On: 09 Jun 2021 17:16:55

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

US3372228

Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 16 Mar 2021 19:23:52

Generated On: 09 Jun 2021 17:16:55

Condition	BURSITIS LEFT ELBOW
Start date (dd MMM yyyy)	UN UNK 1994
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 1994
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1994
Start Year (derived)	1994
Stop Month and Year (derived)	JAN 1994
Stop Year (derived)	1994

US3372228

Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 16 Mar 2021 19:23:52

Generated On: 09 Jun 2021 17:16:55

Condition	LEFT ELBOW BURSA SAC DRAINAGE
Start date (dd MMM yyyy)	UN UNK 1994
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 1994
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1994
Start Year (derived)	1994
Stop Month and Year (derived)	JAN 1994
Stop Year (derived)	1994

US3372228

Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 16 Mar 2021 19:23:52

Generated On: 09 Jun 2021 17:16:55

Condition	BURSITIS LEFT ELBOW
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

US3372228

Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 16 Mar 2021 19:23:52

Generated On: 09 Jun 2021 17:16:55

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

US3372228

Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 16 Mar 2021 19:23:52

Generated On: 09 Jun 2021 17:16:55

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

US3372228

Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 16 Mar 2021 19:23:52

Generated On: 09 Jun 2021 17:16:55

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

US3372228

Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 16 Mar 2021 19:23:52

Generated On: 09 Jun 2021 17:16:55

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

US3372228

Folder: Screening

Form: Medical History (25)

Data signed: (b) (4) 16 Mar 2021 19:23:52

Generated On: 09 Jun 2021 17:16:55

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

US3372228

Folder: Screening

Form: Medical History (26)

Data signed: (b) (4) 16 Mar 2021 19:23:52

Generated On: 09 Jun 2021 17:16:55

Condition	TORN MENISCUS LEFT KNEE
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

US3372228

Folder: Screening

Form: Medical History (27)

Data signed: (b) (4) 16 Mar 2021 19:23:52

Generated On: 09 Jun 2021 17:16:55

Condition	ARTHROSCOPY LEFT KNEE
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

US3372228

Folder: Screening

Form: Medical History (28)

Data signed: (b) (4) 16 Mar 2021 19:23:52

Generated On: 09 Jun 2021 17:16:55

Condition	LEFT FOOT MRSA INFECTION
Start date (dd MMM yyyy)	UN UNK 1996
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 1996
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	JAN 1996
Stop Year (derived)	1996

US3372228

Folder: Screening

Form: Medical History (29)

Data signed: (b) (4) 16 Mar 2021 19:23:52

Generated On: 09 Jun 2021 17:16:55

Condition	OBESITY
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)	_____

US3372228

Folder: Screening

Form: Medical History (30)

Data signed: (b) (4) 16 Mar 2021 19:23:52

Generated On: 09 Jun 2021 17:16:55

Condition	SINUSITIS
Start date (dd MMM yyyy)	UN UNK 2013
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 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

US3372228

Folder: Screening

Form: Medical History (31)

Data signed: (b) (4) 16 Mar 2021 19:23:52

Generated On: 09 Jun 2021 17:16:55

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

US3372228

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 03:30:39

Generated On: 09 Jun 2021 17:16:55

Were vital signs assessed? Yes   
No

Date of assessment (*dd MMM yyyy*) 24 AUG 2020

Time of assessment (*00:00-23:59*) 14:40 (24 HR)

Vital Signs Date and Time (derived) 24 AUG 2020 14:40

Height (*xxx.x*) 194.1 cm

Weight (*xxx.x*) 133.3 kg

BMI (*xxx.x*) 35.38173 kg/m<sup>2</sup>

BMI units KG/M2

Temperature (*xxx.x*) ND - Not Done

Route of measurement Oral   
Axillary   
Other

If Other, specify \_\_\_\_\_

Pulse (*xxx*) ND - Not Done

Pulse units BPM

Respiratory Rate (*xxx*) ND - Not Done

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (*xxx*) ND - Not Done

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (*xxx*) ND - Not Done

Diastolic Blood Pressure units MMHG

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3372228

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 01:08:21

Generated On: 09 Jun 2021 17:16:55

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

24 AUG 2020

---

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

---

US3372228

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 02:18:36

Generated On: 09 Jun 2021 17:16:55

---

**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes  No

---

**Specify** RETIRED

---

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

**No Risk Identified** False

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

US3372228

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 02:18:36

Generated On: 09 Jun 2021 17:16:55

<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)	True
<b>Resides in a single family home</b> (i.e., detached housing)	False
<b>Other</b>	False
<b>Specify</b>	

US3372228

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 03:14:15

Generated On: 09 Jun 2021 17:16:55

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 24 AUG 2020

---

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

---

Folder OID VISIT1

---

US3372228

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 17 Feb 2021 02:01:57

Generated On: 09 Jun 2021 17:16:55

What was the date of randomization? (dd MMM yyyy) 24 AUG 2020

What was the participant's randomization number? 144610

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

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

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

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

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

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

Liver Disease Yes  No

Human Immunodeficiency Virus (HIV) infection Yes  No

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 17 Feb 2021 03:46:58

Generated On: 09 Jun 2021 17:16:55

---

Height	ND - Not Done
Weight	ND - Not Done

---

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 03:46:58

Generated On: 09 Jun 2021 17:16:55

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 ( <i>dd MMM yyyy</i> )	24 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	14:40 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 14:40
Temperature ( <i>xxx.x</i> )	36.4 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	70 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	78 mmHg
Diastolic Blood Pressure units	MMHG

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 03:46:58

Generated On: 09 Jun 2021 17:16:55

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 ( <i>dd MMM yyyy</i> )	24 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	16:25 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 16:25
Temperature ( <i>xxx.x</i> )	36.3 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	66 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	80 mmHg
Diastolic Blood Pressure units	MMHG

US3372228

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 01:08:21

Generated On: 09 Jun 2021 17:16:55

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

24 AUG 2020

---

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

---

US3372228

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 23:44:17

Generated On: 09 Jun 2021 17:16:55

Was study treatment given? Yes   
No

If No, reason not given

Participant declined due to Adverse Event   
Physician withheld dose due to Adverse Event   
Death   
Lost To Follow-Up   
Physician Decision   
Pregnancy   
Protocol Deviation   
Study Terminated by Sponsor   
Withdrawal of Consent by Participant   
Confirmed COVID-19   
Other

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 15:52 (24 HR)

Treatment Date and Time (derived) 24 AUG 2020 15:52

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

US3372228

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 00:04:02

Generated On: 09 Jun 2021 17:16:55

---

Was the sample collected? Yes   
No

---

Collection date (*dd MMM yyyy*) 24 AUG 2020

---

Collection time (*00:00-23:59*) 15:23 (24 HR)

---

Collection date and time (derived) 24 AUG 2020 15:23

---

US3372228

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 17:19:42

Generated On: 09 Jun 2021 17:16:55

---

Collection date ( <i>dd MMM yyyy</i> )			24 AUG 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:20	24 AUG 2020 15:20
Nasopharyngeal Swab 2	No		

---

US3372228

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:42:05

Generated On: 09 Jun 2021 17:16:55

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

**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 97.4 °F

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

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

PC Time Stamp	24 AUG 2020 16:35
PC Open Date & Time	24 AUG 2020 16:12
PC Close Date & Time	24 AUG 2020 18:42

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 97.6 °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 24 AUG 2020 20:16  
PC Open Date & Time 24 AUG 2020 19:37  
PC Close Date & Time 25 AUG 2020 11:59

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:16:55

**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	97.0 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	25 AUG 2020 12:00
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:16:55

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.4 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	26 AUG 2020 12:00
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:16:55

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.5 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	27 AUG 2020 23:59
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:16:55

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.7 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	28 AUG 2020 19:44
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:16:55

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.7 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	29 AUG 2020 17:56
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:16:55

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.8 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	30 AUG 2020 14:01
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

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

Please record - **PAIN AT INJECTION SITE.**  
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity
- Any use of prescription pain  
reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**  
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity
- Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp	24 AUG 2020 16:35
PC Open Date & Time	24 AUG 2020 16:12
PC Close Date & Time	24 AUG 2020 18:42

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	24 AUG 2020 20:17
PC Open Date & Time	24 AUG 2020 19:37
PC Close Date & Time	25 AUG 2020 11:59

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

DAY 2

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

25 AUG 2020 12:01

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

DAY 3

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	26 AUG 2020 12:01
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

DAY 4

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

None

Please select one response below

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

None

Please select one response below

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

27 AUG 2020 23:59

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

DAY 5

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

28 AUG 2020 19:44

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

DAY 6

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

29 AUG 2020 17:57

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

DAY 7

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

30 AUG 2020 14:02

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

**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

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

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

No

Yes

---

PC Time stamp	24 AUG 2020 16:35
PC Open Date & Time	24 AUG 2020 16:12
PC Close Date & Time	24 AUG 2020 18:42

---

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

**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

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

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

No   
Yes

---

PC Time stamp	24 AUG 2020 20:17
PC Open Date & Time	24 AUG 2020 19:37
PC Close Date & Time	25 AUG 2020 11:59

---

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:55

**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

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:55

---

	Yes <input type="checkbox"/>
PC Time stamp	25 AUG 2020 12:01
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

---

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:55

**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

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:55

---

	Yes <input type="checkbox"/>
PC Time stamp	26 AUG 2020 12:01
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

---

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:55

**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

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:55

---

Yes

---

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

---

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:55

**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

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:55

---

	Yes <input type="checkbox"/>
PC Time stamp	28 AUG 2020 19:44
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

---

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:55

**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

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:55

---

	Yes <input type="checkbox"/>
PC Time stamp	29 AUG 2020 17:57
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

---

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:55

**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

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:55

---

	Yes <input type="checkbox"/>
PC Time stamp	30 AUG 2020 14:02
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

---

US3372228

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:35:54

Generated On: 09 Jun 2021 17:16:55

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 31 AUG 2020

---

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

---

Comments

---

*If Contact Not Made, please provide Comments*

---

US3372228

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:42:05

Generated On: 09 Jun 2021 17:16:55

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3372228

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:35:54

Generated On: 09 Jun 2021 17:16:55

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 7 SEP 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3372228

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:42:05

Generated On: 09 Jun 2021 17:16:55

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3372228

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:35:54

Generated On: 09 Jun 2021 17:16:55

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 14 SEP 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3372228

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:42:05

Generated On: 09 Jun 2021 17:16:55

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3372228

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 20:21:29

Generated On: 09 Jun 2021 17:16:55

---

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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

---

US3372228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 20:21:29

Generated On: 09 Jun 2021 17:16:55

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 ( <i>dd MMM yyyy</i> )	28 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	08:33 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 08:33
Temperature ( <i>xxx.x</i> )	36.4 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse ( <i>xxx</i> )	71 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	19 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	73 mmHg
Diastolic Blood Pressure units	MMHG

US3372228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 20:21:29

Generated On: 09 Jun 2021 17:16:55

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 ( <i>dd MMM yyyy</i> )	28 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	09:54 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 09:54
Temperature ( <i>xxx.x</i> )	36.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse ( <i>xxx</i> )	68 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	72 mmHg
Diastolic Blood Pressure units	MMHG

US3372228

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 20:21:29

Generated On: 09 Jun 2021 17:16:55

---

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.*

---

US3372228

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 20:21:29

Generated On: 09 Jun 2021 17:16:55

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) 28 SEP 2020

What was the treatment time? (00:00-23:59) 09:22 (24 HR)

Treatment Date and Time (derived) 28 SEP 2020 09:22

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

US3372228

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 20:21:29

Generated On: 09 Jun 2021 17:16:55

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 28 SEP 2020

---

Collection time (*00:00-23:59*) 08:48 (24 HR)

---

Collection date and time (derived) 28 SEP 2020 08:48

---

US3372228

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 17:19:42

Generated On: 09 Jun 2021 17:16:55

---

Collection date ( <i>dd MMM yyyy</i> )			28 SEP 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:47	28 SEP 2020 08:47
Nasopharyngeal Swab 2	No		

---

US3372228

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:42:05

Generated On: 09 Jun 2021 17:16:55

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

**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 97.0 °F

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

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

PC Time Stamp 28 SEP 2020 10:03

PC Open Date & Time 28 SEP 2020 09:42

PC Close Date & Time 28 SEP 2020 12:12

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 97.5 °F

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

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

PC Time Stamp 28 SEP 2020 22:05  
PC Open Date & Time 28 SEP 2020 13:07  
PC Close Date & Time 29 SEP 2020 11:59

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:16:55

**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	97.6 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	29 SEP 2020 12:00
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:16:55

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.0 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	30 SEP 2020 12:00
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:16:55

**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 \_\_\_\_\_  
Was any **MEDICATION TAKEN** today for pain or fever? Yes   
No

Please confirm reason for pain or fever medication (may select more than one):  
To **TREAT** pain or fever that has already occurred \_\_\_\_\_  
To **PREVENT** pain or fever from occurring \_\_\_\_\_  
PC Time Stamp \_\_\_\_\_  
PC Open Date & Time 01 OCT 2020 12:00  
PC Close Date & Time 02 OCT 2020 11:59

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:16:55

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.4 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	02 OCT 2020 23:59
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:16:55

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.6 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	03 OCT 2020 13:59
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:16:55

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.7 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	04 OCT 2020 12:00
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

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

Please record - **PAIN AT INJECTION SITE.**  
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity
- Any use of prescription pain  
reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**  
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity
- Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp	28 SEP 2020 10:04
PC Open Date & Time	28 SEP 2020 09:42
PC Close Date & Time	28 SEP 2020 12:12

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

**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

28 SEP 2020 22:05

PC Open Date & Time

28 SEP 2020 13:07

PC Close Date & Time

29 SEP 2020 11:59

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

DAY 2

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	29 SEP 2020 12:01
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

DAY 3

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	30 SEP 2020 12:01
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

DAY 4

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

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

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

- Yes
- No

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

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

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

DAY 5

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	02 OCT 2020 23:59
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

DAY 6

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

03 OCT 2020 13:59

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

DAY 7

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

04 OCT 2020 12:01

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

**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

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

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

No

Yes

PC Time stamp	28 SEP 2020 10:04
PC Open Date & Time	28 SEP 2020 09:42
PC Close Date & Time	28 SEP 2020 12:12

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

**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

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

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

No

Yes

---

PC Time stamp	28 SEP 2020 22:06
PC Open Date & Time	28 SEP 2020 13:07
PC Close Date & Time	29 SEP 2020 11:59

---

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:55

**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

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:55

---

	Yes <input type="checkbox"/>
PC Time stamp	29 SEP 2020 12:02
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

---

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:55

**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

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:55

---

	Yes <input type="checkbox"/>
PC Time stamp	30 SEP 2020 12:01
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

---

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:55

**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

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:55

Yes

---

PC Time stamp

---

PC Open Date & Time

01 OCT 2020 12:00

---

PC Close Date & Time

02 OCT 2020 11:59

---

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:55

**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

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:55

---

	Yes <input type="checkbox"/>
PC Time stamp	03 OCT 2020 00:00
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

---

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:55

**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

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:55

---

	Yes <input type="checkbox"/>
PC Time stamp	03 OCT 2020 13:59
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

---

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:55

**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

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:55

---

	Yes <input type="checkbox"/>
PC Time stamp	04 OCT 2020 12:01
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

---

US3372228

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:35:54

Generated On: 09 Jun 2021 17:16:55

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 30 SEP 2020

---

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

---

Comments

---

*If Contact Not Made, please provide Comments*

---

US3372228

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:42:05

Generated On: 09 Jun 2021 17:16:55

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3372228

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:35:54

Generated On: 09 Jun 2021 17:16:55

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 05 OCT 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3372228

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:42:05

Generated On: 09 Jun 2021 17:16:55

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3372228

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:35:54

Generated On: 09 Jun 2021 17:16:55

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 12 OCT 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3372228

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:42:05

Generated On: 09 Jun 2021 17:16:55

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3372228

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 20:02:05

Generated On: 09 Jun 2021 17:16:55

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 19 OCT 2020

---

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

---

Folder OID VISIT3

---

US3372228

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 20:02:05

Generated On: 09 Jun 2021 17:16:55

Were vital signs assessed? Yes   
No

Date of assessment (dd MMM yyyy) \_\_\_\_\_

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral   
Axillary   
Other

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3372228

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 20:02:05

Generated On: 09 Jun 2021 17:16:55

---

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.*

---

US3372228

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 20:02:05

Generated On: 09 Jun 2021 17:16:55

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 19 OCT 2020

---

Collection time (*00:00-23:59*) 12:47 (24 HR)

---

Collection date and time (derived) 19 OCT 2020 12:47

---

US3372228

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:42:05

Generated On: 09 Jun 2021 17:16:55

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3372228

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

<b>TIMEPOINT</b>	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 OCT 2020 15:56:06
Patient Cloud Open Date & Time	24 OCT 2020 00:01
Patient Cloud Close Date & Time	28 OCT 2020 23:59

US3372228

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

**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 31 OCT 2020 10:00:54

Patient Cloud Open Date & Time 31 OCT 2020 00:01

Patient Cloud Close Date & Time 04 NOV 2020 23:59

US3372228

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

**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 08 NOV 2020 09:40:49

Patient Cloud Open Date & Time 07 NOV 2020 00:01

Patient Cloud Close Date & Time 11 NOV 2020 23:59

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

DAY 89

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

No

Yes

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

No

Yes

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

Date and time of submission 19 NOV 2020 23:09:36

Patient Cloud Open Date & Time 18 NOV 2020 00:01

Patient Cloud Close Date & Time 22 NOV 2020 23:59

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

DAY 96

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

No

Yes

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

No

Yes

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

Date and time of submission 25 NOV 2020 13:40:11

Patient Cloud Open Date & Time 25 NOV 2020 00:01

Patient Cloud Close Date & Time 29 NOV 2020 23:59

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

DAY 103

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

No

Yes

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

No

Yes

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

Date and time of submission 02 DEC 2020 16:01:14

Patient Cloud Open Date & Time 02 DEC 2020 00:01

Patient Cloud Close Date & Time 06 DEC 2020 23:59

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 DEC 2020 00:01:48
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

DAY 117

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

No

Yes

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

No

Yes

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

Date and time of submission 16 DEC 2020 00:01:50

Patient Cloud Open Date & Time 16 DEC 2020 00:01

Patient Cloud Close Date & Time 20 DEC 2020 23:59

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

**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 23 DEC 2020 00:01:43

Patient Cloud Open Date & Time 23 DEC 2020 00:01

Patient Cloud Close Date & Time 27 DEC 2020 23:59

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 <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	01 JAN 2021 12:58:31
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 <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	06 JAN 2021 10:02:54
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 <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	15 JAN 2021 12:27:49
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 <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	22 JAN 2021 13:15:02
Patient Cloud Open Date & Time	20 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59

US3372228

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:16:55

---

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
<hr/>		
<hr/>		

US3372228

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:35:54

Generated On: 09 Jun 2021 17:16:55

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 23 NOV 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3372228

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:42:05

Generated On: 09 Jun 2021 17:16:55

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3372228

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 21:05:02

Generated On: 09 Jun 2021 17:16:55

---

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* \_\_\_\_\_

---

US3372228

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 25 Apr 2021 23:04:35

Generated On: 09 Jun 2021 17:16:55

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

---

---

US3372228

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 25 Apr 2021 23:04:35

Generated On: 09 Jun 2021 17:16:55

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* \_\_\_\_\_

US3372228

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 13:45:15

Generated On: 09 Jun 2021 17:16:55

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3372228

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:16:55

---

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

---

US3372228

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:16:55

---

Generate Next COVID-19 Assessment

Yes

No

---

US3372228

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 13:20:59

Generated On: 09 Jun 2021 17:16:55

Was the sample collected? Yes   
No

Collection date (dd MMM yyyy) \_\_\_\_\_

Collection time (00:00-23:59) \_\_\_\_\_

Collection date and time (derived) \_\_\_\_\_

US3372228

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 29 Apr 2021 13:20:59

Generated On: 09 Jun 2021 17:16:55

Was the sample collected? Yes   
No

Collection date (dd MMM yyyy) \_\_\_\_\_

Collection time (00:00 - 23:59) \_\_\_\_\_

Collection Date and Time (derived) \_\_\_\_\_

US3372228

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Feb 2021 16:46:39

Generated On: 09 Jun 2021 17:16:55

---

Did the participant experience any adverse events?

Yes

No

---

If Yes, enter details on the Adverse Events form.

---

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 21 Apr 2021 15:07:19

Generated On: 09 Jun 2021 17:16:55

AEID USA-US056-2021-MRNA-1273-P30  
1000005

Adverse event DEATH-UNKNOWN CAUSE

Was this a medically-attended AE? Yes   
No

Was this a Solicited Adverse Reaction? Yes   
No

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes   
No

Start date (dd MMM yyyy) 25 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes   
No

If not Ongoing, end date (dd MMM yyyy) 25 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild   
Grade 2/Moderate   
Grade 3/Severe   
Grade 4

Is the adverse event serious? Yes   
No

AE is serious due To (check all that apply)

Death True

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes   
No   
Unknown

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 21 Apr 2021 15:07:19

Generated On: 09 Jun 2021 17:16:55

---

Number of Days in ICU \_\_\_\_\_

---

Persistent or significant disability or incapacity False

---

Congenital anomaly or birth defect False

---

Other medically important event False

---

Relationship to investigational product Not Related   
Related   
Not Applicable

---

Relationship to Study Procedure Not Related   
Related   
Not Applicable

---

Action taken with investigational product None   
Dose Delayed   
Investigational Product   
Withdrawn   
Not Applicable

---

Other action taken (check all that apply)

---

None True

---

Concomitant Medication False

---

Concomitant Procedure False

---

Outcome Fatal   
Not Recovered/Not Resolved   
Recovered/Resolved   
Recovered/Resolved with   
Sequelae   
Recovering/Resolving   
Unknown

---

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: \_\_\_\_\_

Narrative

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 21 Apr 2021 15:07:19

Generated On: 09 Jun 2021 17:16:55

---

SUBJECTS WIFE CONTACTED SITE TO REPORT THAT THE SUBJECT PASSED AWAY UNEXPECTEDLY ON 25-JAN-2021. WIFE HAD GONE TO HELP THE SUBJECT OUT OF BED ON THE 25TH OF JAN., THE SUBJECT WAS AWAKE AT THE TIME THEN TOOK A BREATH AND PASSED AWAY. SUBJECT HAD UNDERWENT A CERVICAL FUSION ON 20-JAN-2021 AND DISCHARGED HOME AFTER PROCEDURE WITH NO COMPLICATIONS. CAUSE OF DEATH IS UNKNOWN AND PER THE WIFE THERE WILL BE NO AUTOPSY PERFORMED. DEATH CERTIFICATE WAS REQUESTED FROM THE WIFE WHEN AVAILABLE. SUBJECT WAS UNBLINDED BY THE SITE AND THE SUBJECT HAD RECEIVED PLACEBO.

---

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)	

---

---

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 17 Feb 2021 01:46:05

Generated On: 09 Jun 2021 17:16:55

---

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

Yes

No

---

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

---

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 24 Feb 2021 20:52:21

Generated On: 09 Jun 2021 17:16:55

Name of Medication METFORMIN

Prophylaxis Yes   
No

Indication DIABETES MELLITUS TYPE II

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

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 24 Feb 2021 20:52:21

Generated On: 09 Jun 2021 17:16:55

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 2014

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 24 Feb 2021 20:52:21

Generated On: 09 Jun 2021 17:16:55

Name of Medication FOLIC ACID

Prophylaxis Yes   
No

Indication DIETARY SUPPLEMENT

Dose per administration 5

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

172 of 1759

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 24 Feb 2021 20:52:21

Generated On: 09 Jun 2021 17:16:55

---

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 2014

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 24 Feb 2021 20:52:21

Generated On: 09 Jun 2021 17:16:55

Name of Medication OMEPRAZOLE

Prophylaxis Yes   
No

Indication GASTROESOPHAGEAL REFLUX DISEASE

Dose per administration 20

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal

PRODUCTION RELEASE (v12.003  
EAB) (1725)

174 of 1759

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 24 Feb 2021 20:52:21

Generated On: 09 Jun 2021 17:16:55

---

	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 UNK 2008
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="checkbox"/>
	803 <input type="checkbox"/>
	804 <input checked="" type="radio"/>

---

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 24 Feb 2021 20:52:21

Generated On: 09 Jun 2021 17:16:55

Name of Medication LISINOPRIL

Prophylaxis Yes   
No

Indication HYPERTENSION

Dose per administration 10

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

176 of 1759

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 24 Feb 2021 20:52:21

Generated On: 09 Jun 2021 17:16:55

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify \_\_\_\_\_

Start date (dd MMM yyyy) UN UNK 2000

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 24 Feb 2021 20:52:21

Generated On: 09 Jun 2021 17:16:55

Name of Medication ATENOLOL

Prophylaxis Yes   
No

Indication HYPERTENSION

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

178 of 1759

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 24 Feb 2021 20:52:21

Generated On: 09 Jun 2021 17:16:55

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify \_\_\_\_\_

Start date (dd MMM yyyy) UN UNK 2000

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 24 Feb 2021 20:52:21

Generated On: 09 Jun 2021 17:16:55

Name of Medication AMLODIPINE

Prophylaxis Yes   
No

Indication HYPERTENSION

Dose per administration 5

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 24 Feb 2021 20:52:21

Generated On: 09 Jun 2021 17:16:55

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify \_\_\_\_\_

Start date (dd MMM yyyy) UN UNK 2000

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 24 Feb 2021 20:52:21

Generated On: 09 Jun 2021 17:16:55

Name of Medication ASPIRIN

Prophylaxis Yes   
No

Indication CARDIAC PROPHYLAXIS

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

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 24 Feb 2021 20:52:21

Generated On: 09 Jun 2021 17:16:55

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 2014

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 24 Feb 2021 20:52:21

Generated On: 09 Jun 2021 17:16:55

Name of Medication TRAZADONE

Prophylaxis Yes   
No

Indication DEPRESSION

Dose per administration 300

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

184 of 1759

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 24 Feb 2021 20:52:21

Generated On: 09 Jun 2021 17:16:55

---

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 1990

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 24 Feb 2021 20:52:21

Generated On: 09 Jun 2021 17:16:55

Name of Medication ESZOPICLONE

Prophylaxis Yes   
No

Indication INSOMNIA`

Dose per administration 1

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

186 of 1759

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 24 Feb 2021 20:52:21

Generated On: 09 Jun 2021 17:16:55

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 1990

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 24 Feb 2021 20:52:21

Generated On: 09 Jun 2021 17:16:55

Name of Medication VITAMIN B12 (COBALAMIN)

Prophylaxis Yes   
No

Indication VITAMIN B12 DEFICIENCY

Dose per administration 650

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

188 of 1759

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 24 Feb 2021 20:52:21

Generated On: 09 Jun 2021 17:16:55

---

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 AUG 2019

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 2

---

Interval Dosage Definition (derived) 802   
803   
804

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 24 Feb 2021 20:52:21

Generated On: 09 Jun 2021 17:16:55

Name of Medication TESTOSTERONE CYPIONATE

Prophylaxis Yes   
No

Indication MALE HYPOGONADISM

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

BI-WEEKLY

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

190 of 1759

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 24 Feb 2021 20:52:21

Generated On: 09 Jun 2021 17:16:55

---

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*) UN UNK 2014

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 24 Feb 2021 20:52:21

Generated On: 09 Jun 2021 17:16:55

Name of Medication VITAMIN D

Prophylaxis Yes   
No

Indication DIETARY SUPPLEMENT

Dose per administration 5000

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

192 of 1759

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 24 Feb 2021 20:52:21

Generated On: 09 Jun 2021 17:16:55

---

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (*dd MMM yyyy*) UN JAN 2020

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 24 Feb 2021 20:52:21

Generated On: 09 Jun 2021 17:16:55

Name of Medication VITAMIN C

Prophylaxis Yes   
No

Indication DIETARY SUPPLEMENT

Dose per administration 1000

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

194 of 1759

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 24 Feb 2021 20:52:21

Generated On: 09 Jun 2021 17:16:55

---

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (*dd MMM yyyy*) UN JAN 2020

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 24 Feb 2021 20:52:21

Generated On: 09 Jun 2021 17:16:55

Name of Medication OXYCODONE/ACETAMINOPHE  
N

Prophylaxis Yes   
No

Indication GENERALIZED  
OSTEOARTHRITIS

Dose per administration 10/325

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

196 of 1759

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 24 Feb 2021 20:52:21

Generated On: 09 Jun 2021 17:16:55

---

	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 JUN 2020

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 24 Feb 2021 20:52:21

Generated On: 09 Jun 2021 17:16:55

Name of Medication DIPHTHERIA TETANUS AND  
ACELLULAR PERTUSSIS  
VACCINE

Prophylaxis Yes   
No

Indication DIPHTHERIA TETANUS AND  
ACELLULAR PERTUSSIS  
PROPHYLAXIS/PREVENTION

Dose per administration 0.5

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical

PRODUCTION RELEASE (v12.003  
EAB) (1725)

198 of 1759

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 24 Feb 2021 20:52:21

Generated On: 09 Jun 2021 17:16:55

- Subcutaneous
- Transdermal
- Intraocular
- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify \_\_\_\_\_

Start date (dd MMM yyyy) UN UNK 2012

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) UN UNK 2012

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
804

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 24 Feb 2021 20:52:21

Generated On: 09 Jun 2021 17:16:55

Name of Medication PNEUMONIA VACCINE

Prophylaxis Yes   
No

Indication PNEUMONIA  
PROPHYLAXIS/PREVENTION

Dose per administration 0.5

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 24 Feb 2021 20:52:21

Generated On: 09 Jun 2021 17:16:55

---

	Intraocular	<input type="radio"/>
	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)	UN UNK 2015
Start date completely unknown	False
Ongoing?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

---

If not Ongoing, End date (dd MMM yyyy)	UN UNK 2015
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"/>

---

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 24 Feb 2021 20:52:21

Generated On: 09 Jun 2021 17:16:55

Name of Medication HERPES ZOSTER VACCINE

Prophylaxis Yes   
No

Indication HERPES ZOSTER  
PROPHYLAXIS/PREVENTION

Dose per administration 0.5

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal

PRODUCTION RELEASE (v12.003  
EAB) (1725)

202 of 1759

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 24 Feb 2021 20:52:21

Generated On: 09 Jun 2021 17:16:55

---

	Intraocular	<input type="radio"/>
	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) UN JAN 2019

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) UN JAN 2019

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
804

---

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 24 Feb 2021 20:52:21

Generated On: 09 Jun 2021 17:16:55

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes   
No

Indication INFLUENZA  
PROPHYLAXIS/PREVENTION

Dose per administration 0.5

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal

PRODUCTION RELEASE (v12.003  
EAB) (1725)

204 of 1759

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 24 Feb 2021 20:52:21

Generated On: 09 Jun 2021 17:16:55

---

	Intraocular	<input type="radio"/>
	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) UN AUG 2019

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) UN AUG 2019

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
804

US3372228

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Mar 2021 19:23:52

Generated On: 09 Jun 2021 17:16:55

---

Were any concomitant procedures performed?

Yes

No

---

If yes, please complete Concomitant Procedures form.

---

US3372228

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 16 Mar 2021 19:23:52

Generated On: 09 Jun 2021 17:16:55

Procedure/Surgery date ( <i>dd MMM</i> <i>yyyy</i> )	Procedure/Surgery	Indication	If indication is Other, specify
20 JAN 2021	CERVICAL FUSION	Medical History	

US3372228

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 28 Apr 2021 01:02:58

Generated On: 09 Jun 2021 17:16:55

Date of study discontinuation/completion (*dd MMM yyyy*) 25 JAN 2021

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*) 25 JAN 2021

Was autopsy performed?

Yes

No

Unknown

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 22 Apr 2021 16:38:27

Generated On: 09 Jun 2021 17:16:55

SAEID	USA-US056-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	FLORIDA
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 22 Apr 2021 16:38:27

Generated On: 09 Jun 2021 17:16:55

SAEID	USA-US056-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	FLORIDA
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	29/JAN/2021 13:18
<b>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.</b>	<input checked="" type="checkbox"/> True

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 22 Apr 2021 16:38:27

Generated On: 09 Jun 2021 17:16:55

SAEID	USA-US056-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	FLORIDA
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	03/MAR/2021 09:23
<b>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.</b>	<input checked="" type="checkbox"/> True

Audit

US3372228 (Prod: Palm Beach Research Center)

US3372228

Form: Participant Creation

Generated On: 09 Jun 2021 17:16:55

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:44:39
User entered 'US3372228'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 17:19:28

US3372228

Form: Participant Creation

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47

US3372228

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 03:14:15
User entered 'Yes (Y)'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 18:37:47

US3372228

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:14:15
User entered '24 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 17:19:29

US3372228

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:14:15
User entered 'Clinic (Clinic)'	(b) (4) Kimarie Lee-Russell (b) (4)	24 Aug 2020 18:37:47

US3372228

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'SCRN'	System	24 Aug 2020 18:37:47

US3372228

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:55

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:08:09
User closed query 'Per GCL Lab Reconciliation RQ : As per response "correct year of birth is 1965" .Please update the Date of Birth in EDC.Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Nov 2020 08:47:57
User entered (b) (6) 1965' reason for change: Data Entry Error	RWS_ENDPOINT ENDPOINT (b) (4)	19 Nov 2020 21:45:40
Query 'Per GCL Lab Reconciliation RQ : As per response "correct year of birth is 1965" .Please update the Date of Birth in EDC.Thank you.' answered with 'there is no way to update the date of birth in EDC, a DCF has been filed with endpoint which I stated already.' (Site from DM).	Peter Jacob (b) (4) (b) (4)	17 Nov 2020 20:45:13
User opened query 'Per GCL Lab Reconciliation RQ : As per response "correct year of birth is 1965" .Please update the Date of Birth in EDC.Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 11:10:26
User closed query 'Per GCL Lab Reconciliation RQ : Please confirm the correct Year of Birth recorded. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 11:10:26
Query 'Per GCL Lab Reconciliation RQ : Please confirm the correct Year of Birth recorded. Thank you.' answered with 'correct year of birth is 1965' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 18:06:55
User opened query 'Per GCL Lab Reconciliation RQ : Please confirm the correct Year of Birth recorded. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 12:43:53
User closed query 'Per GCL Lab Reconciliation: Swab for Visit1 Day1, Visit2 Day29 Year of Birth (1956) recorded on this form does not match with the Year of birth (1965) reported in PPD Central lab. Please reconcile the correct date and update if confirmed. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 12:43:53

US3372228

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:55

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Swab for Visit1 Day1, Visit2 Day29 Year of Birth (1956) recorded on this form does not match with the Year of birth (1965) reported in PPD Central lab. Please reconcile the correct date and update if confirmed. Else clarify, thank you.' answered with 'DCF was filed in endpoint ' (Site from DM).	Peter Jacob (b) (4)	07 Nov 2020 00:27:54
User opened query 'Per GCL Lab Reconciliation: Swab for Visit1 Day1, Visit2 Day29 Year of Birth (1956) recorded on this form does not match with the Year of birth (1965) reported in PPD Central lab. Please reconcile the correct date and update if confirmed. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 05:52:46
User entered (b) (6) 1956'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 17:19:30

US3372228

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:55

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	16 Feb 2021 23:08:09
User closed query 'Age does not fit Date of Birth.' (Site from System).	System	19 Nov 2020 21:45:40
User opened query 'Age does not fit Date of Birth.' (Site from System).	System	07 Nov 2020 00:28:03
User entered '55' reason for change: Data Entry Error	Peter Jacob (b) (4) (b) (4)	07 Nov 2020 00:28:03
User closed query 'Age does not fit Date of Birth.' (Site from System).	System	04 Oct 2020 13:49:10
User entered '64' reason for change: Data Entry Error	David Scott (b) (4) (b) (4)	04 Oct 2020 13:49:10
User opened query 'Age does not fit Date of Birth.' (Site from System).	System	24 Aug 2020 19:12:51
User entered '55'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 18:38:00

US3372228

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:55

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'YEARS'	System	24 Aug 2020 18:38:00

US3372228

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:55

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '55'	System	19 Nov 2020 21:45:40
User entered '64'	System	24 Aug 2020 19:12:51

US3372228

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:55

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	16 Feb 2021 23:08:09
User entered 'Male (M)'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 18:38:00

US3372228

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:55

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	16 Feb 2021 23:08:09
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 18:38:00

US3372228

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:55

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	16 Feb 2021 23:08:09
User entered '1'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 18:38:00

US3372228

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:55

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	16 Feb 2021 23:08:09
User entered '0'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 18:38:00

US3372228

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:55

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	16 Feb 2021 23:08:09
User entered '0'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 18:38:00

US3372228

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:55

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	16 Feb 2021 23:08:09
User entered '0'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 18:38:00

US3372228

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:55

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	16 Feb 2021 23:08:09
User entered '0'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 18:38:00

US3372228

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:55

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	16 Feb 2021 23:08:09
User entered '0'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 18:38:00

US3372228

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:55

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	16 Feb 2021 23:08:09
User entered empty.	Kimarie Lee-Russell (b) (4)	24 Aug 2020 18:38:00

US3372228

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:55

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	16 Feb 2021 23:08:09
User entered '0'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 18:38:00

US3372228

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:55

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	16 Feb 2021 23:08:09
User entered '0'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 18:38:00

US3372228

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:55

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:26:38
User entered '24 Aug 2020'	(b) (4) Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:12:51

US3372228

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Aug 2020'	System	24 Aug 2020 19:12:51

US3372228

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '2020'	System	24 Aug 2020 19:12:51

US3372228

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:55

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:26:38
User entered 'Amendment 2 (2)'	(b) (4) Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:12:51

US3372228

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	16 Feb 2021 23:26:38
User entered 'Yes (Y)'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:12:51

US3372228

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:55

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	16 Feb 2021 23:26:38
User entered empty.	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:12:51

US3372228

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:55

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	16 Feb 2021 23:26:38
User entered empty.	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:12:51

US3372228

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:55

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	16 Feb 2021 23:26:38
User entered 'No (N)'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:12:51

US3372228

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:55

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	16 Feb 2021 23:26:38
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 17:19:29

US3372228

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:55

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '1'	System	24 Aug 2020 19:13:27

US3372228

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 00:20:25
User entered 'Yes (Y)'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:13:27

US3372228

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:16:55

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:52:38
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 20:19:10
	(b) (4)	

US3372228

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4)	04 Nov 2020 20:54:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Nov 2020 20:54:15
Data point term sent to Coder	System	04 Nov 2020 20:24:05
User entered 'diabetes mellitus type II'	Peter Jacob (b) (4)	04 Nov 2020 20:24:01

US3372228

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 2014'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 20:24:01

US3372228

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 20:24:01

US3372228

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 20:24:01
	(b) (4)	

US3372228

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:23:52
Signature has been broken.	(b) (4) Peter Jacob (b) (4)	15 Mar 2021 21:33:51
User signature succeeded.	(b) (4) Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered empty.	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 20:24:01
	(b) (4)	

US3372228

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 20:24:01

US3372228

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 2014'	System	04 Nov 2020 20:24:01

US3372228

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '2014'	System	04 Nov 2020 20:24:01

US3372228

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered empty.	System	04 Nov 2020 20:24:01

US3372228

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered empty.	System	04 Nov 2020 20:24:01

US3372228

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	(b) (4)	04 Nov 2020 21:09:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Nov 2020 21:09:33
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4)	04 Nov 2020 20:54:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Nov 2020 20:54:25
Data point term sent to Coder	System	04 Nov 2020 20:26:06
User entered 'hypertension'	Peter Jacob (b) (4)	04 Nov 2020 20:25:48
	(b) (4)	

US3372228

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 2014'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 20:25:48

US3372228

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 20:25:48

US3372228

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 20:25:48

US3372228

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 20:25:48

US3372228

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 20:25:48

US3372228

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 2014'	System	04 Nov 2020 20:25:48

US3372228

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '2014'	System	04 Nov 2020 20:25:48

US3372228

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered empty.	System	04 Nov 2020 20:25:48

US3372228

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered empty.	System	04 Nov 2020 20:25:48

US3372228

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 20:54:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 20:54:57
Data point term sent to Coder	System	04 Nov 2020 20:35:23
User entered 'gastroesophageal reflux disease'	Peter Jacob (b) (4)	04 Nov 2020 20:35:00

US3372228

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 2008'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 20:35:00

US3372228

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 20:35:00

US3372228

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 20:35:00

US3372228

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered empty.	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 20:35:00

US3372228

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 20:35:00

US3372228

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 2008'	System	04 Nov 2020 20:35:00

US3372228

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '2008'	System	04 Nov 2020 20:35:00

US3372228

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered empty.	System	04 Nov 2020 20:35:00

US3372228

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered empty.	System	04 Nov 2020 20:35:00

US3372228

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 00:36:30
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 21:10:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 21:10:32
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 20:55:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 20:55:16
Data point term sent to Coder	System	04 Nov 2020 20:40:33
User entered 'depression'	Peter Jacob (b) (4) (b) (4)	04 Nov 2020 20:39:43

US3372228

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 1990'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 20:39:43

US3372228

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 20:39:43

US3372228

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 20:39:43
	(b) (4)	

US3372228

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 20:39:43

US3372228

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 20:39:43
	(b) (4)	

US3372228

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 1990'	System	04 Nov 2020 20:39:43

US3372228

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '1990'	System	04 Nov 2020 20:39:43

US3372228

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered empty.	System	04 Nov 2020 20:39:43

US3372228

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered empty.	System	04 Nov 2020 20:39:43

US3372228

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\23.0.	Coder Import (b) (4)	04 Nov 2020 21:10:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Nov 2020 21:10:33
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\23.0.	Coder Import (b) (4)	04 Nov 2020 20:55:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Nov 2020 20:55:20
Data point term sent to Coder	System	04 Nov 2020 20:41:33
User entered 'insomnia'	Peter Jacob (b) (4)	04 Nov 2020 20:40:51

US3372228

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 1990'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 20:40:51

US3372228

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 20:40:51

US3372228

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 20:40:51
	(b) (4)	

US3372228

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered empty.	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 20:40:51

US3372228

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:55

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 20:40:51

US3372228

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 1990'	System	04 Nov 2020 20:40:51

US3372228

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '1990'	System	04 Nov 2020 20:40:51

US3372228

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered empty.	System	04 Nov 2020 20:40:51

US3372228

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered empty.	System	04 Nov 2020 20:40:51

US3372228

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
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)	04 Nov 2020 21:10:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Nov 2020 21:10:33
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)	04 Nov 2020 20:55:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Nov 2020 20:55:21
Data point term sent to Coder	System	04 Nov 2020 20:41:34
User entered 'vitamin B12 deficiency'	Peter Jacob (b) (4)	04 Nov 2020 20:41:31

US3372228

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un Aug 2019'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 20:41:31

US3372228

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 20:41:31

US3372228

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 00:36:30
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	04 Nov 2020 20:41:31

US3372228

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered empty.	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 20:41:31

US3372228

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 20:41:31

US3372228

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Aug 2019'	System	04 Nov 2020 20:41:31

US3372228

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '2019'	System	04 Nov 2020 20:41:31

US3372228

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered empty.	System	04 Nov 2020 20:41:31

US3372228

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered empty.	System	04 Nov 2020 20:41:31

US3372228

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User coded data point as SOC: Endocrine disorders, HLT: Male gonadal function disorders, PT: Hypogonadism male, LLT: Hypogonadism male - version MedDRA\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Nov 2020 21:10:37
Data point term sent to Coder	(b) (4)	
User entered 'male hypogonadism'	System	04 Nov 2020 20:47:43
	Peter Jacob (b) (4)	04 Nov 2020 20:47:38
	(b) (4)	

US3372228

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 2014'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 20:47:38

US3372228

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 20:47:38

US3372228

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 20:47:38
	(b) (4)	

US3372228

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 20:47:38

US3372228

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 20:47:38

US3372228

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 2014'	System	04 Nov 2020 20:47:38

US3372228

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '2014'	System	04 Nov 2020 20:47:38

US3372228

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered empty.	System	04 Nov 2020 20:47:38

US3372228

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered empty.	System	04 Nov 2020 20:47:38

US3372228

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Generalized osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 20:57:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 20:57:34
Data point term sent to Coder	System	04 Nov 2020 20:55:08
User entered 'generalized osteoarthritis'	Peter Jacob (b) (4)	04 Nov 2020 20:54:55

US3372228

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un Jun 2020'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 20:54:55
	(b) (4)	

US3372228

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 20:54:55

US3372228

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 20:54:55
	(b) (4)	

US3372228

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered empty.	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 20:54:55
	(b) (4)	

US3372228

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 20:54:55

US3372228

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jun 2020'	System	04 Nov 2020 20:54:55

US3372228

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '2020'	System	04 Nov 2020 20:54:55

US3372228

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered empty.	System	04 Nov 2020 20:54:55

US3372228

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered empty.	System	04 Nov 2020 20:54:55

US3372228

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Cervical disc herniation - version MedDRA\23.0.	Coder Import (b) (4)	04 Nov 2020 20:58:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Nov 2020 20:58:31
Data point term sent to Coder	System	04 Nov 2020 20:57:12
User entered 'herniated disc cervical spine'	Peter Jacob (b) (4)	04 Nov 2020 20:57:09

US3372228

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 2016'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 20:57:09

US3372228

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 20:57:09

US3372228

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 20:57:09

US3372228

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered empty.	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 20:57:09

US3372228

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 20:57:09

US3372228

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 2016'	System	04 Nov 2020 20:57:09

US3372228

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '2016'	System	04 Nov 2020 20:57:09

US3372228

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered empty.	System	04 Nov 2020 20:57:09

US3372228

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered empty.	System	04 Nov 2020 20:57:09

US3372228

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:16:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Chronic tonsillitis, LLT: Chronic tonsillitis - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 21:07:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 21:07:29
Data point term sent to Coder	System	04 Nov 2020 21:06:30
User entered 'tonsillitis - chronic'	Peter Jacob (b) (4)	04 Nov 2020 21:06:08

US3372228

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 1984'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 21:06:08

US3372228

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 21:06:08

US3372228

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
	(b) (4)	
User entered 'No (N)'	Peter Jacob (b) (4)	04 Nov 2020 21:06:08
	(b) (4)	

US3372228

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 1986'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 21:06:08

US3372228

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:16:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 21:06:08

US3372228

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:16:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 1984'	System	04 Nov 2020 21:06:08

US3372228

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:16:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '1984'	System	04 Nov 2020 21:06:08

US3372228

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 1986'	System	04 Nov 2020 21:06:08

US3372228

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '1986'	System	04 Nov 2020 21:06:08

US3372228

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:16:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 00:36:30
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 21:48:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 21:48:29
Data point term sent to Coder	System	04 Nov 2020 21:32:14
User entered 'tonsillectomy'	Peter Jacob (b) (4) (b) (4)	04 Nov 2020 21:31:52

US3372228

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 1986'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 21:31:52

US3372228

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 21:31:52

US3372228

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 21:31:52
	(b) (4)	

US3372228

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 1986'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 21:31:52

US3372228

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:16:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 21:31:52

US3372228

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:16:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 1986'	System	04 Nov 2020 21:31:52

US3372228

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:16:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '1986'	System	04 Nov 2020 21:31:52

US3372228

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 1986'	System	04 Nov 2020 21:31:52

US3372228

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '1986'	System	04 Nov 2020 21:31:52

US3372228

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:16:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Soft tissue neoplasms benign, HLT: Soft tissue neoplasms benign NEC, PT: Lipoma, LLT: Lipoma - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 04:54:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 04:54:36
Data point term sent to Coder	System	04 Nov 2020 21:52:47
User entered 'right armpit benign lipoma'	Peter Jacob (b) (4)	04 Nov 2020 21:52:21

US3372228

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 1996'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 21:52:21

US3372228

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 21:52:21

US3372228

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
	(b) (4)	
User entered 'No (N)'	Peter Jacob (b) (4)	04 Nov 2020 21:52:21
	(b) (4)	

US3372228

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 1996'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 21:52:21

US3372228

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:16:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 21:52:21

US3372228

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:16:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 1996'	System	04 Nov 2020 21:52:21

US3372228

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:16:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '1996'	System	04 Nov 2020 21:52:21

US3372228

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 1996'	System	04 Nov 2020 21:52:21

US3372228

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '1996'	System	04 Nov 2020 21:52:21

US3372228

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:16:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User coded data point as SOC: Surgical and medical procedures, HLGT: Soft tissue therapeutic procedures, HLT: Soft tissue therapeutic procedures NEC, PT: Lipoma excision, LLT: Lipoma excision - version MedDRA\23.0.	Coder Import (b) (4)	13 Nov 2020 12:28:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	13 Nov 2020 12:28:47
Data point term sent to Coder	System	04 Nov 2020 21:54:51
User entered 'right armpit lipoma enucleation'	Peter Jacob (b) (4)	04 Nov 2020 21:54:48

US3372228

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 1996'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 21:54:48

US3372228

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 21:54:48

US3372228

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 21:54:48

US3372228

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 1996'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 21:54:48

US3372228

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:16:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 21:54:48

US3372228

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:16:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 1996'	System	04 Nov 2020 21:54:48

US3372228

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '1996'	System	04 Nov 2020 21:54:48

US3372228

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 1996'	System	04 Nov 2020 21:54:48

US3372228

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '1996'	System	04 Nov 2020 21:54:48

US3372228

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:16:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Cholelithiasis - version MedDRA\23.0.	Coder Import (b) (4)	04 Nov 2020 22:12:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Nov 2020 22:12:42
Data point term sent to Coder	System	04 Nov 2020 22:12:12
User entered 'cholelithiasis'	Peter Jacob (b) (4)	04 Nov 2020 22:11:59

US3372228

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 2008'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 22:11:59

US3372228

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 22:11:59

US3372228

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 22:11:59
	(b) (4)	

US3372228

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 2008'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 22:11:59

US3372228

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:16:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 22:11:59
	(b) (4)	

US3372228

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:16:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 2008'	System	04 Nov 2020 22:11:59

US3372228

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '2008'	System	04 Nov 2020 22:11:59

US3372228

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 2008'	System	04 Nov 2020 22:11:59

US3372228

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '2008'	System	04 Nov 2020 22:11:59

US3372228

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:16:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User coded data point as SOC: Surgical and medical procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 22:14:37
Data point term sent to Coder	(b) (4)	
User entered 'cholecystectomy'	Coder Import (b) (4)	04 Nov 2020 22:14:37
	System	04 Nov 2020 22:14:14
	Peter Jacob (b) (4)	04 Nov 2020 22:13:49
	(b) (4)	

US3372228

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 2008'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 22:13:49

US3372228

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 22:13:49

US3372228

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 22:13:49
	(b) (4)	

US3372228

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 2008'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 22:13:49

US3372228

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:16:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 22:13:49

US3372228

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:16:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 2008'	System	04 Nov 2020 22:13:49

US3372228

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:16:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '2008'	System	04 Nov 2020 22:13:49

US3372228

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 2008'	System	04 Nov 2020 22:13:49

US3372228

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '2008'	System	04 Nov 2020 22:13:49

US3372228

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:16:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Thoracic disc herniation - version MedDRA\23.0.	Coder Import (b) (4)	04 Nov 2020 22:26:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Nov 2020 22:26:34
Data point term sent to Coder	System	04 Nov 2020 22:25:51
User entered 'herniated disc thoracic spine'	Peter Jacob (b) (4)	04 Nov 2020 22:25:25

US3372228

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 1996'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 22:25:25

US3372228

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 22:25:25

US3372228

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 22:25:25

US3372228

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 2016'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 22:25:25

US3372228

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:16:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 22:25:25
	(b) (4)	

US3372228

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:16:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 1996'	System	04 Nov 2020 22:25:25

US3372228

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:16:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '1996'	System	04 Nov 2020 22:25:25

US3372228

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 2016'	System	04 Nov 2020 22:25:25

US3372228

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '2016'	System	04 Nov 2020 22:25:25

US3372228

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:16:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User coded data point as SOC: Surgical and medical procedures, HLG: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal fusion surgery, LLT: Spinal fusion - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 22:43:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 22:43:30
Data point term sent to Coder	System	04 Nov 2020 22:42:15
User entered 'thoracic spine fusion'	Peter Jacob (b) (4)	04 Nov 2020 22:41:59

US3372228

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 2016'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 22:41:59

US3372228

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 22:41:59

US3372228

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 22:41:59
	(b) (4)	

US3372228

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 2016'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 22:41:59

US3372228

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:16:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 22:41:59

US3372228

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:16:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 2016'	System	04 Nov 2020 22:41:59

US3372228

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:16:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '2016'	System	04 Nov 2020 22:41:59

US3372228

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 2016'	System	04 Nov 2020 22:41:59

US3372228

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '2016'	System	04 Nov 2020 22:41:59

US3372228

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:16:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Synovial and bursal disorders, HLT: Bursal disorders, PT: Bursitis, LLT: Elbow bursitis - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 23:00:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 23:00:32
Data point term sent to Coder	System	04 Nov 2020 22:44:16
User entered 'bursitis left elbow'	Peter Jacob (b) (4)	04 Nov 2020 22:44:07

US3372228

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 1994'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 22:44:07

US3372228

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 22:44:07

US3372228

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 22:44:07
	(b) (4)	

US3372228

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 1994'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 22:44:07

US3372228

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:16:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 22:44:07

US3372228

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:16:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 1994'	System	04 Nov 2020 22:44:07

US3372228

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '1994'	System	04 Nov 2020 22:44:07

US3372228

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 1994'	System	04 Nov 2020 22:44:07

US3372228

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '1994'	System	04 Nov 2020 22:44:07

US3372228

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:16:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Joint fluid drainage, LLT: Joint fluid drainage - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 07:42:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 07:42:10
Data point term sent to Coder	System	04 Nov 2020 22:51:19
User entered 'left elbow bursa sac drainage'	Peter Jacob (b) (4)	04 Nov 2020 22:50:59

US3372228

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 1994'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 22:50:59

US3372228

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 22:50:59

US3372228

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 22:50:59
	(b) (4)	

US3372228

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 1994'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 22:50:59

US3372228

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:16:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 22:50:59

US3372228

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:16:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 1994'	System	04 Nov 2020 22:50:59

US3372228

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:16:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '1994'	System	04 Nov 2020 22:50:59

US3372228

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 1994'	System	04 Nov 2020 22:50:59

US3372228

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '1994'	System	04 Nov 2020 22:50:59

US3372228

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:16:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Synovial and bursal disorders, HLT: Bursal disorders, PT: Bursitis, LLT: Elbow bursitis - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 22:57:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 22:57:30
Data point term sent to Coder	System	04 Nov 2020 22:56:23
User entered 'bursitis left elbow'	Peter Jacob (b) (4)	04 Nov 2020 22:55:45

US3372228

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 2015'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 22:55:45

US3372228

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 22:55:45

US3372228

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 22:55:45
	(b) (4)	

US3372228

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'UN UNK 2016' reason for change: Data Entry Error	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 22:55:58
User entered 'un UNK 2015'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 22:55:45

US3372228

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:16:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 22:55:45

US3372228

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:16:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 2015'	System	04 Nov 2020 22:55:45

US3372228

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:16:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '2015'	System	04 Nov 2020 22:55:45

US3372228

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 2016'	System	04 Nov 2020 22:55:58
User entered 'Jan 2015'	System	04 Nov 2020 22:55:45

US3372228

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '2016'	System	04 Nov 2020 22:55:58
User entered '2015'	System	04 Nov 2020 22:55:45

US3372228

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:16:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Bone and joint infections, PT: Arthritis infective, LLT: Joint infection - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 12:26:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 12:26:44
Data point term sent to Coder	System	04 Nov 2020 22:58:25
User entered 'left elbow mycobacterium infection'	Peter Jacob (b) (4)	04 Nov 2020 22:57:51

US3372228

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 2016'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 22:57:51

US3372228

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 22:57:51

US3372228

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 22:57:51

US3372228

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 2016'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 22:57:51

US3372228

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:16:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 00:36:30
User entered '0'	Peter Jacob (b) (4) (b) (4)	04 Nov 2020 22:57:51

US3372228

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:16:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 2016'	System	04 Nov 2020 22:57:51

US3372228

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:16:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '2016'	System	04 Nov 2020 22:57:51

US3372228

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 2016'	System	04 Nov 2020 22:57:51

US3372228

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '2016'	System	04 Nov 2020 22:57:51

US3372228

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:16:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User coded data point as SOC: Surgical and medical procedures, HLGT: Soft tissue therapeutic procedures, HLT: Fascial and bursal therapeutic procedures, PT: Bursa removal, LLT: Bursectomy - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 05:11:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 05:11:44
Data point term sent to Coder	System	04 Nov 2020 22:59:26
User entered 'left elbow bursectomy'	Peter Jacob (b) (4)	04 Nov 2020 22:58:53

US3372228

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 2016'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 22:58:53

US3372228

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 22:58:53

US3372228

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 22:58:53

US3372228

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 2016'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 22:58:53

US3372228

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:16:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 22:58:53

US3372228

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:16:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 2016'	System	04 Nov 2020 22:58:53

US3372228

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:16:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '2016'	System	04 Nov 2020 22:58:53

US3372228

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 2016'	System	04 Nov 2020 22:58:53

US3372228

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '2016'	System	04 Nov 2020 22:58:53

US3372228

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:16:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Meniscus injury, LLT: Meniscus tear of knee - version MedDRA\23.0.	Coder Import (b) (4)	04 Nov 2020 23:01:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Nov 2020 23:01:36
Data point term sent to Coder	System	04 Nov 2020 23:00:27
User entered 'torn meniscus right knee'	Peter Jacob (b) (4)	04 Nov 2020 22:59:30

US3372228

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 2014'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 22:59:30

US3372228

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 22:59:30

US3372228

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
	(b) (4)	
User entered 'No (N)'	Peter Jacob (b) (4)	04 Nov 2020 22:59:30
	(b) (4)	

US3372228

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 2016'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 22:59:30

US3372228

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:16:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 22:59:30

US3372228

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:16:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 2014'	System	04 Nov 2020 22:59:30

US3372228

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:16:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '2014'	System	04 Nov 2020 22:59:30

US3372228

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 2016'	System	04 Nov 2020 22:59:30

US3372228

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '2016'	System	04 Nov 2020 22:59:30

US3372228

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:16:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Cartilage injury, LLT: Cartilage tear in knee - version MedDRA\23.0.	Coder Import (b) (4)	04 Nov 2020 23:05:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Nov 2020 23:05:30
Data point term sent to Coder	System	04 Nov 2020 23:04:31
User entered 'torn cartilage right knee'	Peter Jacob (b) (4)	04 Nov 2020 23:04:28
	(b) (4)	

US3372228

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 2016'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 23:04:28

US3372228

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 23:04:28

US3372228

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 23:04:28

US3372228

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 2016'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 23:04:28

US3372228

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:16:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 23:04:28

US3372228

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:16:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 2016'	System	04 Nov 2020 23:04:28

US3372228

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:16:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '2016'	System	04 Nov 2020 23:04:28

US3372228

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 2016'	System	04 Nov 2020 23:04:28

US3372228

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '2016'	System	04 Nov 2020 23:04:28

US3372228

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 17:16:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User coded data point as SOC: Investigations, HLT: Musculoskeletal and soft tissue investigations (excl enzyme tests), HLT: Musculoskeletal and soft tissue imaging procedures, PT: Arthroscopy, LLT: Arthroscopy R knee - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 23:09:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 23:09:30
Data point term sent to Coder	System	04 Nov 2020 23:08:34
User entered 'arthroscopy right knee'	Peter Jacob (b) (4)	04 Nov 2020 23:08:00

US3372228

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 2016'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 23:08:00

US3372228

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 23:08:00

US3372228

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
	(b) (4)	
User entered 'No (N)'	Peter Jacob (b) (4)	04 Nov 2020 23:08:00
	(b) (4)	

US3372228

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 2016'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 23:08:00

US3372228

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 17:16:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 23:08:00
	(b) (4)	

US3372228

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 17:16:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 2016'	System	04 Nov 2020 23:08:00

US3372228

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 17:16:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '2016'	System	04 Nov 2020 23:08:00

US3372228

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 2016'	System	04 Nov 2020 23:08:00

US3372228

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '2016'	System	04 Nov 2020 23:08:00

US3372228

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 17:16:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Meniscus injury, LLT: Meniscus tear of knee - version MedDRA\23.0.	Coder Import (b) (4)	04 Nov 2020 23:21:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Nov 2020 23:21:35
Data point term sent to Coder	System	04 Nov 2020 23:20:43
User entered 'torn meniscus left knee'	Peter Jacob (b) (4)	04 Nov 2020 23:20:04

US3372228

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 2018'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 23:20:04

US3372228

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 23:20:04

US3372228

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 23:20:04
	(b) (4)	

US3372228

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 2018'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 23:20:04

US3372228

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 17:16:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 23:20:04

US3372228

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 17:16:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 2018'	System	04 Nov 2020 23:20:04

US3372228

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 17:16:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '2018'	System	04 Nov 2020 23:20:04

US3372228

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 2018'	System	04 Nov 2020 23:20:04

US3372228

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '2018'	System	04 Nov 2020 23:20:04

US3372228

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 17:16:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User coded data point as SOC: Investigations, HLT: Musculoskeletal and soft tissue investigations (excl enzyme tests), HLT: Musculoskeletal and soft tissue imaging procedures, PT: Arthroscopy, LLT: Arthroscopy L knee - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 23:22:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 23:22:37
Data point term sent to Coder	System	04 Nov 2020 23:21:44
User entered 'arthroscopy left knee'	Peter Jacob (b) (4)	04 Nov 2020 23:21:12

US3372228

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 2018'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 23:21:12

US3372228

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 23:21:12

US3372228

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 23:21:12
	(b) (4)	

US3372228

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 2018'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 23:21:12

US3372228

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 17:16:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 23:21:12

US3372228

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 17:16:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 2018'	System	04 Nov 2020 23:21:12

US3372228

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 17:16:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '2018'	System	04 Nov 2020 23:21:12

US3372228

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 2018'	System	04 Nov 2020 23:21:12

US3372228

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '2018'	System	04 Nov 2020 23:21:12

US3372228

Folder: Screening

Form: Medical History (28)

Generated On: 09 Jun 2021 17:16:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Staphylococcal infections, PT: Staphylococcal infection, LLT: Infection MRSA - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 05:11:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 05:11:43
Data point term sent to Coder	System	04 Nov 2020 23:22:45
User entered 'left foot mrsa infection'	Peter Jacob (b) (4)	04 Nov 2020 23:21:47

US3372228

Folder: Screening

Form: Medical History (28)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 1996'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 23:21:47

US3372228

Folder: Screening

Form: Medical History (28)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 23:21:47

US3372228

Folder: Screening

Form: Medical History (28)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 23:21:47

US3372228

Folder: Screening

Form: Medical History (28)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 1996'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 23:21:47

US3372228

Folder: Screening

Form: Medical History (28)

Generated On: 09 Jun 2021 17:16:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 23:21:47
	(b) (4)	

US3372228

Folder: Screening

Form: Medical History (28)

Generated On: 09 Jun 2021 17:16:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 1996'	System	04 Nov 2020 23:21:47

US3372228

Folder: Screening

Form: Medical History (28)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '1996'	System	04 Nov 2020 23:21:47

US3372228

Folder: Screening

Form: Medical History (28)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 1996'	System	04 Nov 2020 23:21:47

US3372228

Folder: Screening

Form: Medical History (28)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '1996'	System	04 Nov 2020 23:21:47

US3372228

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 17:16:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User coded data point as SOC: Metabolism and nutrition disorders, HLG T: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 23:39:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 23:39:32
Data point term sent to Coder	System	04 Nov 2020 23:22:45
User entered 'obesity'	Peter Jacob (b) (4)	04 Nov 2020 23:22:12

US3372228

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 2019'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 23:22:12

US3372228

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 23:22:12

US3372228

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 23:22:12
	(b) (4)	

US3372228

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 23:22:12

US3372228

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 17:16:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 23:22:12

US3372228

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 17:16:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 2019'	System	04 Nov 2020 23:22:12

US3372228

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 17:16:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '2019'	System	04 Nov 2020 23:22:12

US3372228

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered empty.	System	04 Nov 2020 23:22:12

US3372228

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered empty.	System	04 Nov 2020 23:22:12

US3372228

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 17:16:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Sinusitis - version MedDRA\23.0.	Coder Import (b) (4)	04 Nov 2020 23:23:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Nov 2020 23:23:40
Data point term sent to Coder	System	04 Nov 2020 23:22:45
User entered 'sinusitis'	Peter Jacob (b) (4)	04 Nov 2020 23:22:23
	(b) (4)	

US3372228

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 2013'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 23:22:23

US3372228

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 23:22:23

US3372228

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 23:22:23
	(b) (4)	

US3372228

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 2014'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 23:22:23

US3372228

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 17:16:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 23:22:23

US3372228

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 17:16:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 2013'	System	04 Nov 2020 23:22:23

US3372228

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '2013'	System	04 Nov 2020 23:22:23

US3372228

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 2014'	System	04 Nov 2020 23:22:23

US3372228

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '2014'	System	04 Nov 2020 23:22:23

US3372228

Folder: Screening

Form: Medical History (31)

Generated On: 09 Jun 2021 17:16:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 00:36:30
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Paranasal therapeutic procedures, PT: Functional endoscopic sinus surgery, LLT: Functional endoscopic sinus surgery - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 09:08:11
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 09:08:11
Data point term sent to Coder	System	04 Nov 2020 23:22:45
User entered 'left nostril sinus endoscopic'	Peter Jacob (b) (4) (b) (4)	04 Nov 2020 23:22:37

US3372228

Folder: Screening

Form: Medical History (31)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 2014'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 23:22:37
	(b) (4)	

US3372228

Folder: Screening

Form: Medical History (31)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 23:22:37

US3372228

Folder: Screening

Form: Medical History (31)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
	(b) (4)	
User entered 'No (N)'	Peter Jacob (b) (4)	04 Nov 2020 23:22:37
	(b) (4)	

US3372228

Folder: Screening

Form: Medical History (31)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered 'un UNK 2014'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 23:22:37
	(b) (4)	

US3372228

Folder: Screening

Form: Medical History (31)

Generated On: 09 Jun 2021 17:16:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 23:22:37

US3372228

Folder: Screening

Form: Medical History (31)

Generated On: 09 Jun 2021 17:16:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 2014'	System	04 Nov 2020 23:22:37

US3372228

Folder: Screening

Form: Medical History (31)

Generated On: 09 Jun 2021 17:16:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '2014'	System	04 Nov 2020 23:22:37

US3372228

Folder: Screening

Form: Medical History (31)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'Jan 2014'	System	04 Nov 2020 23:22:37

US3372228

Folder: Screening

Form: Medical History (31)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '2014'	System	04 Nov 2020 23:22:37

US3372228

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:30:39
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:13:10

US3372228

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:30:39
User entered '24 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:13:10

US3372228

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:30:39
User entered '14:40'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:13:10

US3372228

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '24 Aug 2020 14:40'	System	01 Sep 2020 15:13:10

US3372228

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:30:39
User entered '194.1' cm	(b) (4) Peter Jacob (b) (4)	01 Sep 2020 15:13:10
DataPoint set to visible.	(b) (4) System	24 Aug 2020 19:13:27

US3372228

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:30:39
User entered '133.3' kg	(b) (4) Peter Jacob (b) (4)	01 Sep 2020 15:13:10
DataPoint set to visible.	(b) (4) System	24 Aug 2020 19:13:27

US3372228

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '35.38173'	System	01 Sep 2020 15:13:10
DataPoint set to visible.	System	24 Aug 2020 19:13:27

US3372228

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'kg/m2'	System	01 Sep 2020 15:13:10
DataPoint set to visible.	System	24 Aug 2020 19:13:27

US3372228

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:30:39
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 07:08:54
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 17:14:46
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 17:14:36
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 05:33:53
User entered '36.4' C	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:13:10

US3372228

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:30:39
	(b) (4)	
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	06 Oct 2020 17:14:36
	(b) (4)	
User entered 'Oral (Oral)'	Peter Jacob (b) (4)	01 Sep 2020 15:13:10
	(b) (4)	

US3372228

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:30:39
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:13:10

US3372228

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:30:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	06 Oct 2020 17:14:36
User entered '70'	Peter Jacob (b) (4)	01 Sep 2020 15:13:10
	(b) (4)	

US3372228

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'bpm'	System	01 Sep 2020 15:13:10

US3372228

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:30:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	06 Oct 2020 17:14:36
User entered '18'	Peter Jacob (b) (4)	01 Sep 2020 15:13:10
	(b) (4)	

US3372228

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'breaths/min'	System	01 Sep 2020 15:13:10

US3372228

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:30:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	06 Oct 2020 17:14:36
User entered '140'	Peter Jacob (b) (4)	01 Sep 2020 15:13:10
	(b) (4)	

US3372228

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'mmHg'	System	01 Sep 2020 15:13:10

US3372228

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:30:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	06 Oct 2020 17:14:36
User entered '78'	Peter Jacob (b) (4)	01 Sep 2020 15:13:10
	(b) (4)	

US3372228

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'mmHg'	System	01 Sep 2020 15:13:10

US3372228

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30

US3372228

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30

US3372228

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:08:21
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:13:19

US3372228

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:08:21
User entered '24 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:13:19

US3372228

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 02:18:36
User entered 'No (N)'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:14:29

US3372228

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

[Emergency Response](#) (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 02:18:36
User entered 'No (N)'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:14:29

US3372228

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 02:18:36
User entered 'No (N)'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:14:29

US3372228

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:18:36
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:14:29

US3372228

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 02:18:36
User entered 'No (N)'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:14:29

US3372228

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:18:36
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:14:29

US3372228

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:18:36
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:14:29

US3372228

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 02:18:36
User entered 'No (N)'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:14:29

US3372228

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 02:18:36
User entered 'No (N)'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:14:29

US3372228

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 02:18:36
User entered 'No (N)'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:14:29

US3372228

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 02:18:36
User entered 'No (N)'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:14:29

US3372228

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 02:18:36
User entered 'Yes (Y)'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:14:29

US3372228

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:18:36
	(b) (4)	
User entered 'RETIRED' reason for change: Data Entry Error	Peter Jacob (b) (4)	01 Sep 2020 15:13:42
	(b) (4)	
User entered 'Retired Military'	Kimarie Lee-Russell	24 Aug 2020 19:14:29
	(b) (4)	

US3372228

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 02:18:36
User entered '0'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:14:29

US3372228

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 02:18:36
User entered '0'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:14:29

US3372228

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

[Resides in Multi-family dwelling](#) (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 02:18:36
User entered '0'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:14:29

US3372228

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 02:18:36
User entered '0'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:14:29

US3372228

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 02:18:36
User entered '1'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:14:29

US3372228

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 02:18:36
User entered '0'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:14:29

US3372228

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 02:18:36
User entered '0'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:14:29

US3372228

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 02:18:36
User entered empty.	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:14:29

US3372228

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 03:14:15
User entered 'Yes (Y)'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:14:41

US3372228

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:14:15
User entered '24 Aug 2020'	(b) (4) Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:14:41

US3372228

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 03:14:15
User entered 'Clinic (Clinic)'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:14:41

US3372228

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'VISIT1'	System	24 Aug 2020 19:14:41

US3372228

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:01:57
User entered '24 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 19:19:24

US3372228

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:55

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:01:57
User entered '144610'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 19:19:24

US3372228

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:55

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 02:01:57
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 19:19:24

US3372228

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:55

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 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 02:01:57
User entered 'No (N)'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:15:16

US3372228

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:55

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 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 02:01:57
User entered 'No (N)'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:15:16

US3372228

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:55

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 02:01:57
User entered 'No (N)'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:15:16

US3372228

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:55

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 02:01:57
User entered 'Yes (Y)'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:15:16

US3372228

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:55

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 02:01:57
User entered 'No (N)'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:15:16

US3372228

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:55

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:01:57
User closed query 'Per CDM: This field requires yes or no. Please complete.' (Site from DM).	(b) (4)	05 Nov 2020 15:49:40
Query 'Per CDM: This field requires yes or no. Please complete.' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 15:49:40
Query 'Per CDM: This field requires yes or no. Please complete.' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4)	04 Nov 2020 20:15:48
User entered 'No (N)'	(b) (4)	04 Nov 2020 20:15:48
User entered 'No (N)'	Peter Jacob (b) (4)	04 Nov 2020 20:15:44
User opened query 'Per CDM: This field requires yes or no. Please complete.' (Site from DM).	(b) (4)	29 Oct 2020 16:12:06
User opened query 'Per CDM: This field requires yes or no. Please complete.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 16:12:06
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:40:10
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:41:29

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:46:58
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 07:39:52
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 17:15:46
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 17:15:19
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 05:33:58
User entered '194.1' cm	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:15:33

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:55

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 03:46:58
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 17:15:19
User entered '133.3' kg	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:15:33

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:46:58
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 07:39:52
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 17:15:46
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 17:15:19
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 05:33:58
User entered '194.1' cm	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:15:33

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:55

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 03:46:58
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 17:15:19
User entered '133.3' kg	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:15:33

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User accepted default value 'Pre-Dose (PREDOSE)'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:15:33

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:46:58
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:15:33

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:46:58
User entered '24 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:15:33

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:46:58
User entered '14:40'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:15:33

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '24 Aug 2020 14:40'	System	01 Sep 2020 15:15:33

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 03:46:58
User entered '36.4' C	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:15:33

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:46:58
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:15:33

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:46:58
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:15:33

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:46:58
User entered '70'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:15:33

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'bpm'	System	01 Sep 2020 15:15:33

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:46:58
User entered '18'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:15:33

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'breaths/min'	System	01 Sep 2020 15:15:33

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 03:46:58
User entered '140'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:15:33

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'mmHg'	System	01 Sep 2020 15:15:33

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:46:58
User entered '78'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:15:33

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'mmHg'	System	01 Sep 2020 15:15:33

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:46:58
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 07:39:52
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 17:15:46
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 17:15:19
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 05:33:58
User entered '194.1' cm	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:15:33

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:55

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 03:46:58
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 17:15:19
User entered '133.3' kg	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:15:33

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User accepted default value 'Post-Dose (POSTDOSE)'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:15:57

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:46:58
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:15:57

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:46:58
User entered '24 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:15:57

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:46:58
Query 'Per CDM: Post-dose vital signs evaluation time is less than 60 minutes after IP injection. Please reconcile and update as needed. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:50:40
User opened query 'Per CDM: Post-dose vital signs evaluation time is less than 60 minutes after IP injection. Please reconcile and update as needed. ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 22:00:50
User entered '16:25'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:15:57

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '24 Aug 2020 16:25'	System	01 Sep 2020 15:15:57

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 03:46:58
User entered '36.3' C	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:15:57

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:46:58
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:15:57

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:46:58
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:15:57

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:46:58
User entered '66'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:15:57

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'bpm'	System	01 Sep 2020 15:15:57

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:46:58
User entered '18'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:15:57

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'breaths/min'	System	01 Sep 2020 15:15:57

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:46:58
User entered '134'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:15:57

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'mmHg'	System	01 Sep 2020 15:15:57

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:46:58
User entered '80'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:15:57

US3372228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'mmHg'	System	01 Sep 2020 15:15:57

US3372228

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:08:21
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:16:08

US3372228

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:08:21
User entered '24 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:16:08

US3372228

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	16 Feb 2021 23:44:17
User entered 'Yes (Y)'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:55:12

US3372228

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	16 Feb 2021 23:44:17
User entered empty.	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:55:12

US3372228

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	16 Feb 2021 23:44:17
User entered empty.	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:55:12

US3372228

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'MRNA-1273 OR PLACEBO'	System	24 Aug 2020 19:55:12

US3372228

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:44:17
User entered '24 Aug 2020'	(b) (4) Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:55:12

US3372228

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	16 Feb 2021 23:44:17
User entered '15:52'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:55:12

US3372228

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '24 Aug 2020 15:52'	System	24 Aug 2020 19:55:12

US3372228

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:44:17
User entered 'Left Arm (LEFT ARM)'	(b) (4) Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:55:12

US3372228

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'ONCE'	System	24 Aug 2020 19:55:12

US3372228

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered 'INTRAMUSCULAR'	System	24 Aug 2020 19:55:12

US3372228

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 00:04:02
User entered 'Yes (Y)'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:55:31

US3372228

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:04:02
User entered '24 Aug 2020'	(b) (4) Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:55:31

US3372228

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 00:04:02
User entered '15:23'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:55:31

US3372228

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '24 Aug 2020 15:23'	System	24 Aug 2020 19:55:31

US3372228

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:16:55

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:19:42
User entered '24 Aug 2020'	(b) (4) Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:55:44

US3372228

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:55:44

US3372228

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	16 Feb 2021 17:19:42
User entered 'Yes (Y)'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:55:44

US3372228

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	16 Feb 2021 17:19:42
User entered '15:20'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:55:44

US3372228

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '24 Aug 2020 15:20'	System	24 Aug 2020 19:55:44

US3372228

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:55:44

US3372228

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	16 Feb 2021 17:19:42
User entered 'No (N)'	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:55:44

US3372228

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	16 Feb 2021 17:19:42
User entered empty.	Kimarie Lee-Russell (b) (4)	24 Aug 2020 19:55:44

US3372228

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered empty.	System	24 Aug 2020 19:55:44

US3372228

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:42:05
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	01 Sep 2020 15:16:20

US3372228

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '1'	System	01 Sep 2020 15:16:20

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:55:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-24T16:34:40', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'fefbf85e-7d6a-40ad-a235-d720ddff5a65'	System	24 Aug 2020 20:35:08
User entered 'Yes (Y)'	System	24 Aug 2020 20:35:08

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-24T16:34:54', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'fefbf85e-7d6a-40ad-a235-d720ddff5a65' User entered '97.4'	System	24 Aug 2020 20:35:08
	System	24 Aug 2020 20:35:08

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-24T16:34:59', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'fefbf85e-7d6a-40ad-a235-d720ddff5a65'	System	24 Aug 2020 20:35:08
User entered 'No (N)'	System	24 Aug 2020 20:35:08

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-24T16:35:05', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'fefbf85e-7d6a-40ad-a235-d720ddff5a65'	System	24 Aug 2020 20:35:08
User entered '24 Aug 2020 16:35'	System	24 Aug 2020 20:35:08

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '24 Aug 2020 16:12'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '24 Aug 2020 18:42'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:55:12
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-24T20:16:23', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '50d58b6c-cf73-4d40-9f66-a2cbba363aec' User entered 'Yes (Y)'	System	25 Aug 2020 00:16:40
	System	25 Aug 2020 00:16:40

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-24T20:16:30', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '50d58b6c-cf73-4d40-9f66-a2cbba363aec' User entered '97.6'	System	25 Aug 2020 00:16:40
	System	25 Aug 2020 00:16:40

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-24T20:16:34', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '50d58b6c-cf73-4d40-9f66-a2cbba363aec'	System	25 Aug 2020 00:16:40
User entered 'No (N)'	System	25 Aug 2020 00:16:40

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-24T20:16:38', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '50d58b6c-cf73-4d40-9f66-a2cbba363aec' User entered '24 Aug 2020 20:16'	System	25 Aug 2020 00:16:40
	System	25 Aug 2020 00:16:40

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '24 Aug 2020 19:37'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:55:12
User entered 'Day 2'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:16:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-25T12:00:22', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'f9ae3f1f-0f08-46e3-ac73-400a920690f9' User entered 'Yes (Y)'	System	25 Aug 2020 16:00:53
	System	25 Aug 2020 16:00:53

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:16:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-25T12:00:29', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'f9ae3f1f-0f08-46e3-ac73-400a920690f9' User entered '97.0'	System	25 Aug 2020 16:00:53
	System	25 Aug 2020 16:00:53

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-25T12:00:33', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'f9ae3f1f-0f08-46e3-ac73-400a920690f9' User entered 'No (N)'	System	25 Aug 2020 16:00:53
	System	25 Aug 2020 16:00:53

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-25T12:00:46', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'f9ae3f1f-0f08-46e3-ac73-400a920690f9' User entered '25 Aug 2020 12:00'	System	25 Aug 2020 16:00:53
	System	25 Aug 2020 16:00:53

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:55:12
User entered 'Day 3'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:16:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-26T12:00:32', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '86b76ae4-890d-4b6b-b199-d7cea8c5b334' User entered 'Yes (Y)'	System	26 Aug 2020 16:00:58
	System	26 Aug 2020 16:00:58

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:16:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-26T12:00:38', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '86b76ae4-890d-4b6b-b199-d7cea8c5b334' User entered '97.4'	System	26 Aug 2020 16:00:58
	System	26 Aug 2020 16:00:58

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-26T12:00:41', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '86b76ae4-890d-4b6b-b199-d7cea8c5b334'	System	26 Aug 2020 16:00:58
User entered 'No (N)'	System	26 Aug 2020 16:00:58

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-26T12:00:44', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '86b76ae4-890d-4b6b-b199-d7cea8c5b334' User entered '26 Aug 2020 12:00'	System	26 Aug 2020 16:00:58
	System	26 Aug 2020 16:00:58

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:55:12
User entered 'Day 4'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:16:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-27T23:59:23', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '3bd78a43-352d-4232-8b60-772d49cd8260' User entered 'Yes (Y)'	System	28 Aug 2020 03:59:40
	System	28 Aug 2020 03:59:40

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:16:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-27T23:59:29', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '3bd78a43-352d-4232-8b60-772d49cd8260' User entered '97.5'	System	28 Aug 2020 03:59:40
	System	28 Aug 2020 03:59:40

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-27T23:59:33', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '3bd78a43-352d-4232-8b60-772d49cd8260'	System	28 Aug 2020 03:59:40
User entered 'No (N)'	System	28 Aug 2020 03:59:40

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-27T23:59:37', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '3bd78a43-352d-4232-8b60-772d49cd8260' User entered '27 Aug 2020 23:59'	System	28 Aug 2020 03:59:40
	System	28 Aug 2020 03:59:40

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:55:12
User entered 'Day 5'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:16:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-28T19:43:54', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'fba6c87b-003f-4e9a-9359-1dc6fe69ea34' User entered 'Yes (Y)'	System	28 Aug 2020 23:44:09
	System	28 Aug 2020 23:44:09

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:16:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-28T19:43:59', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'fba6c87b-003f-4e9a-9359-1dc6fe69ea34' User entered '97.7'	System	28 Aug 2020 23:44:09
	System	28 Aug 2020 23:44:09

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-28T19:44:03', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'fba6c87b-003f-4e9a-9359-1dc6fe69ea34'	System	28 Aug 2020 23:44:09
User entered 'No (N)'	System	28 Aug 2020 23:44:09

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-28T19:44:06', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'fba6c87b-003f-4e9a-9359-1dc6fe69ea34' User entered '28 Aug 2020 19:44'	System	28 Aug 2020 23:44:09
	System	28 Aug 2020 23:44:09

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:55:12
User entered 'Day 6'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:16:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-29T17:56:41', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'b4bb3496-f3e4-45e0-8034-051924f8239a' User entered 'Yes (Y)'	System	29 Aug 2020 21:56:56
	System	29 Aug 2020 21:56:56

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:16:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-29T17:56:46', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'b4bb3496-f3e4-45e0-8034-051924f8239a' User entered '97.7'	System	29 Aug 2020 21:56:56
	System	29 Aug 2020 21:56:56

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-29T17:56:49', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'b4bb3496-f3e4-45e0-8034-051924f8239a' User entered 'No (N)'	System	29 Aug 2020 21:56:56
	System	29 Aug 2020 21:56:56

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-29T17:56:52', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'b4bb3496-f3e4-45e0-8034-051924f8239a' User entered '29 Aug 2020 17:56'	System	29 Aug 2020 21:56:56
	System	29 Aug 2020 21:56:56

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:55:12
User entered 'Day 7'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:16:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-30T14:01:14', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '30d6121b-ba2b-479a-855a-9e4d21b7bf1' User entered 'Yes (Y)'	System	30 Aug 2020 18:01:33
	System	30 Aug 2020 18:01:33

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:16:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-30T14:01:21', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '30d6121b-ba2b-479a-855a-9e4d21b7bf1' User entered '97.8'	System	30 Aug 2020 18:01:33
	System	30 Aug 2020 18:01:33

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-30T14:01:25', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '30d6121b-ba2b-479a-855a-9e4d21b7bf1'	System	30 Aug 2020 18:01:33
User entered 'No (N)'	System	30 Aug 2020 18:01:33

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-30T14:01:31', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '30d6121b-ba2b-479a-855a-9e4d21b7bf1' User entered '30 Aug 2020 14:01'	System	30 Aug 2020 18:01:33
	System	30 Aug 2020 18:01:33

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:55:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-24T16:35:13', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'c09d062a-223b-4056-9345-5bedd86c4ca4'	System	24 Aug 2020 20:35:52
User entered 'None (1)'	System	24 Aug 2020 20:35:52

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-24T16:35:17', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'c09d062a-223b-4056-9345-5bedd86c4ca4' User entered 'No (N)'	System	24 Aug 2020 20:35:52
	System	24 Aug 2020 20:35:52

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-24T16:35:20', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'c09d062a-223b-4056-9345-5bedd86c4ca4' User entered 'No (N)'	System	24 Aug 2020 20:35:52
	System	24 Aug 2020 20:35:52

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-24T16:35:24', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'c09d062a-223b-4056-9345-5bedd86c4ca4'	System	24 Aug 2020 20:35:52
User entered 'None (1)'	System	24 Aug 2020 20:35:52

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-24T16:35:27', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'c09d062a-223b-4056-9345-5bedd86c4ca4' User entered '24 Aug 2020 16:35'	System	24 Aug 2020 20:35:52
	System	24 Aug 2020 20:35:52

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '24 Aug 2020 16:12'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '24 Aug 2020 18:42'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:55:12
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-24T20:16:46', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '2c1f9862-2f45-45e5-b2e4-bff5e0f2c053'	System	25 Aug 2020 00:17:10
User entered 'None (1)'	System	25 Aug 2020 00:17:10

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-24T20:16:49', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '2c1f9862-2f45-45e5-b2e4-bff5e0f2c053'	System	25 Aug 2020 00:17:10
User entered 'No (N)'	System	25 Aug 2020 00:17:10

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-24T20:16:54', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '2c1f9862-2f45-45e5-b2e4-bff5e0f2c053'	System	25 Aug 2020 00:17:10
User entered 'No (N)'	System	25 Aug 2020 00:17:10

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-24T20:17:04', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '2c1f9862-2f45-45e5-b2e4-bff5e0f2c053'	System	25 Aug 2020 00:17:10
User entered 'None (1)'	System	25 Aug 2020 00:17:10

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-24T20:17:07', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '2c1f9862-2f45-45e5-b2e4-bff5e0f2c053'	System	25 Aug 2020 00:17:10
User entered '24 Aug 2020 20:17'	System	25 Aug 2020 00:17:10

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '24 Aug 2020 19:37'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:55:12
User entered 'Day 2'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:16:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-25T12:00:51', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'f61b1b98-652a-4e0a-b209-d29fb1da8d00'	System	25 Aug 2020 16:01:21
User entered 'None (1)'	System	25 Aug 2020 16:01:21

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-25T12:00:55', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'f61b1b98-652a-4e0a-b209-d29fb1da8d00' User entered 'No (N)'	System	25 Aug 2020 16:01:21
	System	25 Aug 2020 16:01:21

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-25T12:00:58', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'f61b1b98-652a-4e0a-b209-d29fb1da8d00' User entered 'No (N)'	System	25 Aug 2020 16:01:21
	System	25 Aug 2020 16:01:21

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:16:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-25T12:01:03', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'f61b1b98-652a-4e0a-b209-d29fb1da8d00'	System	25 Aug 2020 16:01:21
User entered 'None (1)'	System	25 Aug 2020 16:01:21

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-25T12:01:05', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'f61b1b98-652a-4e0a-b209-d29fb1da8d00' User entered '25 Aug 2020 12:01'	System	25 Aug 2020 16:01:21
	System	25 Aug 2020 16:01:21

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:55:12
User entered 'Day 3'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:16:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-26T12:00:48', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '0ddeb0f6-fc33-40f1-b722-70c2b8597fc0'	System	26 Aug 2020 16:01:25
User entered 'None (1)'	System	26 Aug 2020 16:01:25

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-26T12:00:51', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '0ddeb0f6-fc33-40f1-b722-70c2b8597fc0' User entered 'No (N)'	System	26 Aug 2020 16:01:25
	System	26 Aug 2020 16:01:25

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-26T12:00:54', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '0ddeb0f6-fc33-40f1-b722-70c2b8597fc0' User entered 'No (N)'	System	26 Aug 2020 16:01:25
	System	26 Aug 2020 16:01:25

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:16:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-26T12:00:58', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '0ddeb0f6-fc33-40f1-b722-70c2b8597fc0'	System	26 Aug 2020 16:01:25
User entered 'None (1)'	System	26 Aug 2020 16:01:25

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-26T12:01:00', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '0ddeb0f6-fc33-40f1-b722-70c2b8597fc0' User entered '26 Aug 2020 12:01'	System	26 Aug 2020 16:01:25
	System	26 Aug 2020 16:01:25

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:55:12
User entered 'Day 4'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:16:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-27T23:59:42', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '65d2161e-e257-40ff-9720-ddd627a8e98a' User entered 'None (1)'	System	28 Aug 2020 04:00:07
	System	28 Aug 2020 04:00:07

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-27T23:59:45', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '65d2161e-e257-40ff-9720-ddd627a8e98a' User entered 'No (N)'	System	28 Aug 2020 04:00:07
	System	28 Aug 2020 04:00:07

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-27T23:59:51', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '65d2161e-e257-40ff-9720-ddd627a8e98a' User entered 'No (N)'	System	28 Aug 2020 04:00:07
	System	28 Aug 2020 04:00:07

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:16:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-27T23:59:54', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '65d2161e-e257-40ff-9720-ddd627a8e98a' User entered 'None (1)'	System	28 Aug 2020 04:00:07
	System	28 Aug 2020 04:00:07

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-27T23:59:59', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '65d2161e-e257-40ff-9720-ddd627a8e98a' User entered '27 Aug 2020 23:59'	System	28 Aug 2020 04:00:07
	System	28 Aug 2020 04:00:07

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:55:12
User entered 'Day 5'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:16:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-28T19:44:09', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '6eacf929-a0ab-4729-ad53-e121257634be' User entered 'None (1)'	System	28 Aug 2020 23:44:25
	System	28 Aug 2020 23:44:25

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-28T19:44:12', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '6eacf929-a0ab-4729-ad53-e121257634be' User entered 'No (N)'	System	28 Aug 2020 23:44:25
	System	28 Aug 2020 23:44:25

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-28T19:44:16', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '6eacf929-a0ab-4729-ad53-e121257634be' User entered 'No (N)'	System	28 Aug 2020 23:44:25
	System	28 Aug 2020 23:44:25

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:16:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-28T19:44:18', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '6eacf929-a0ab-4729-ad53-e121257634be' User entered 'None (1)'	System	28 Aug 2020 23:44:25
	System	28 Aug 2020 23:44:25

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-28T19:44:21', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '6eacf929-a0ab-4729-ad53-e121257634be' User entered '28 Aug 2020 19:44'	System	28 Aug 2020 23:44:25
	System	28 Aug 2020 23:44:25

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:55:12
User entered 'Day 6'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:16:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-29T17:56:56', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'dd72f056-f3de-40d2-acd1-09009bb0ce46' User entered 'None (1)'	System	29 Aug 2020 21:57:14
	System	29 Aug 2020 21:57:14

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-29T17:57:02', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'dd72f056-f3de-40d2-acd1-09009bb0ce46'	System	29 Aug 2020 21:57:14
User entered 'No (N)'	System	29 Aug 2020 21:57:14

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-29T17:57:06', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'dd72f056-f3de-40d2-acd1-09009bb0ce46' User entered 'No (N)'	System	29 Aug 2020 21:57:14
	System	29 Aug 2020 21:57:14

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:16:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-29T17:57:09', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'dd72f056-f3de-40d2-acd1-09009bb0ce46' User entered 'None (1)'	System	29 Aug 2020 21:57:14
	System	29 Aug 2020 21:57:14

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-29T17:57:11', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'dd72f056-f3de-40d2-acd1-09009bb0ce46' User entered '29 Aug 2020 17:57'	System	29 Aug 2020 21:57:14
	System	29 Aug 2020 21:57:14

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:55:12
User entered 'Day 7'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:16:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-30T14:01:43', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '13e93a61-2044-48c4-bb27-a6da98d9e262' User entered 'None (1)'	System	30 Aug 2020 18:02:05
	System	30 Aug 2020 18:02:05

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-30T14:01:46', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '13e93a61-2044-48c4-bb27-a6da98d9e262'	System	30 Aug 2020 18:02:05
User entered 'No (N)'	System	30 Aug 2020 18:02:05

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-30T14:01:50', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '13e93a61-2044-48c4-bb27-a6da98d9e262'	System	30 Aug 2020 18:02:05
User entered 'No (N)'	System	30 Aug 2020 18:02:05

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:16:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-30T14:01:56', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '13e93a61-2044-48c4-bb27-a6da98d9e262'	System	30 Aug 2020 18:02:05
User entered 'None (1)'	System	30 Aug 2020 18:02:05

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-30T14:02:02', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '13e93a61-2044-48c4-bb27-a6da98d9e262' User entered '30 Aug 2020 14:02'	System	30 Aug 2020 18:02:05
	System	30 Aug 2020 18:02:05

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:55:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-24T16:35:32', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'de096afa-fc3f-45c8-9109-ae52822d3159' User entered 'None (0)'	System	24 Aug 2020 20:35:59
	System	24 Aug 2020 20:35:59

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-24T16:35:35', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'de096afa-fc3f-45c8-9109-ae52822d3159' User entered 'None (0)'	System	24 Aug 2020 20:35:59
	System	24 Aug 2020 20:35:59

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-24T16:35:38', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'de096afa-fc3f-45c8-9109-ae52822d3159' User entered 'None (0)'	System	24 Aug 2020 20:35:59
	System	24 Aug 2020 20:35:59

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-24T16:35:41', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'de096afa-fc3f-45c8-9109-ae52822d3159' User entered 'None (0)'	System	24 Aug 2020 20:35:59
	System	24 Aug 2020 20:35:59

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-24T16:35:44', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'de096afa-fc3f-45c8-9109-ae52822d3159' User entered 'None (0)'	System	24 Aug 2020 20:35:59
	System	24 Aug 2020 20:35:59

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-24T16:35:46', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'de096afa-fc3f-45c8-9109-ae52822d3159' User entered 'None (0)'	System	24 Aug 2020 20:35:59
	System	24 Aug 2020 20:35:59

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-24T16:35:50', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'de096afa-fc3f-45c8-9109-ae52822d3159' User entered 'No (N)'	System	24 Aug 2020 20:35:59
	System	24 Aug 2020 20:35:59

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-24T16:35:52', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'de096afa-fc3f-45c8-9109-ae52822d3159' User entered '24 Aug 2020 16:35'	System	24 Aug 2020 20:35:59
	System	24 Aug 2020 20:35:59

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '24 Aug 2020 16:12'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '24 Aug 2020 18:42'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:55:12
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-24T20:17:14', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'c8084ae2-e284-4d49-8314-307960fabe5d' User entered 'None (0)'	System	25 Aug 2020 00:17:46
	System	25 Aug 2020 00:17:46

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-24T20:17:17', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'c8084ae2-e284-4d49-8314-307960fabe5d' User entered 'None (0)'	System	25 Aug 2020 00:17:46
	System	25 Aug 2020 00:17:46

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-24T20:17:21', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'c8084ae2-e284-4d49-8314-307960fabe5d' User entered 'None (0)'	System	25 Aug 2020 00:17:46
	System	25 Aug 2020 00:17:46

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-24T20:17:26', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'c8084ae2-e284-4d49-8314-307960fabe5d' User entered 'None (0)'	System	25 Aug 2020 00:17:46
	System	25 Aug 2020 00:17:46

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-24T20:17:29', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'c8084ae2-e284-4d49-8314-307960fabe5d' User entered 'None (0)'	System	25 Aug 2020 00:17:46
	System	25 Aug 2020 00:17:46

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-24T20:17:32', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'c8084ae2-e284-4d49-8314-307960fabe5d' User entered 'None (0)'	System	25 Aug 2020 00:17:46
	System	25 Aug 2020 00:17:46

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-24T20:17:41', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'c8084ae2-e284-4d49-8314-307960fabe5d' User entered 'No (N)'	System	25 Aug 2020 00:17:46
	System	25 Aug 2020 00:17:46

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-24T20:17:44', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'c8084ae2-e284-4d49-8314-307960fabe5d' User entered '24 Aug 2020 20:17'	System	25 Aug 2020 00:17:46
	System	25 Aug 2020 00:17:46

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '24 Aug 2020 19:37'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:55:12
User entered 'Day 2'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-25T12:01:10', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'd61c7337-c824-42af-802d-2ba1291b8fbf' User entered 'None (0)'	System	25 Aug 2020 16:01:55
	System	25 Aug 2020 16:01:55

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-25T12:01:13', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'd61c7337-c824-42af-802d-2ba1291b8fbf' User entered 'None (0)'	System	25 Aug 2020 16:01:55
	System	25 Aug 2020 16:01:55

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-25T12:01:18', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'd61c7337-c824-42af-802d-2ba1291b8fbf' User entered 'None (0)'	System	25 Aug 2020 16:01:55
	System	25 Aug 2020 16:01:55

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-25T12:01:23', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'd61c7337-c824-42af-802d-2ba1291b8fbf' User entered 'None (0)'	System	25 Aug 2020 16:01:55
	System	25 Aug 2020 16:01:55

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-25T12:01:25', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'd61c7337-c824-42af-802d-2ba1291b8fbf' User entered 'None (0)'	System	25 Aug 2020 16:01:55
	System	25 Aug 2020 16:01:55

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-25T12:01:28', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'd61c7337-c824-42af-802d-2ba1291b8fbf' User entered 'None (0)'	System	25 Aug 2020 16:01:55
	System	25 Aug 2020 16:01:55

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-25T12:01:34', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'd61c7337-c824-42af-802d-2ba1291b8fbf' User entered 'No (N)'	System	25 Aug 2020 16:01:55
	System	25 Aug 2020 16:01:55

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-25T12:01:36', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'd61c7337-c824-42af-802d-2ba1291b8fbf' User entered '25 Aug 2020 12:01'	System	25 Aug 2020 16:01:55
	System	25 Aug 2020 16:01:55

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:55:12
User entered 'Day 3'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-26T12:01:05', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '895a4613-3d9c-4f99-95c6-dda6a93bea35' User entered 'None (0)'	System	26 Aug 2020 16:01:56
	System	26 Aug 2020 16:01:56

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-26T12:01:07', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '895a4613-3d9c-4f99-95c6-dda6a93bea35' User entered 'None (0)'	System	26 Aug 2020 16:01:56
	System	26 Aug 2020 16:01:56

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-26T12:01:11', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '895a4613-3d9c-4f99-95c6-dda6a93bea35' User entered 'None (0)'	System	26 Aug 2020 16:01:56
	System	26 Aug 2020 16:01:56

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-26T12:01:13', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '895a4613-3d9c-4f99-95c6-dda6a93bea35' User entered 'None (0)'	System	26 Aug 2020 16:01:56
	System	26 Aug 2020 16:01:56

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-26T12:01:16', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '895a4613-3d9c-4f99-95c6-dda6a93bea35' User entered 'None (0)'	System	26 Aug 2020 16:01:56
	System	26 Aug 2020 16:01:56

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-26T12:01:18', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '895a4613-3d9c-4f99-95c6-dda6a93bea35' User entered 'None (0)'	System	26 Aug 2020 16:01:56
	System	26 Aug 2020 16:01:56

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-26T12:01:21', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '895a4613-3d9c-4f99-95c6-dda6a93bea35' User entered 'No (N)'	System	26 Aug 2020 16:01:56
	System	26 Aug 2020 16:01:56

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-26T12:01:25', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '895a4613-3d9c-4f99-95c6-dda6a93bea35' User entered '26 Aug 2020 12:01'	System	26 Aug 2020 16:01:56
	System	26 Aug 2020 16:01:56

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:55:12
User entered 'Day 4'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-28T00:00:07', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '6bcc7426-57ed-4fd3-b181-0bbf05acf453' User entered 'None (0)'	System	28 Aug 2020 04:00:41
	System	28 Aug 2020 04:00:41

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-28T00:00:12', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '6bcc7426-57ed-4fd3-b181-0bbf05acf453' User entered 'None (0)'	System	28 Aug 2020 04:00:41
	System	28 Aug 2020 04:00:41

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-28T00:00:16', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '6bcc7426-57ed-4fd3-b181-0bbf05acf453'	System	28 Aug 2020 04:00:41
User entered 'None (0)'	System	28 Aug 2020 04:00:41

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-28T00:00:18', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '6bcc7426-57ed-4fd3-b181-0bbf05acf453' User entered 'None (0)'	System	28 Aug 2020 04:00:41
	System	28 Aug 2020 04:00:41

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-28T00:00:21', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '6bcc7426-57ed-4fd3-b181-0bbf05acf453' User entered 'None (0)'	System	28 Aug 2020 04:00:41
	System	28 Aug 2020 04:00:41

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-28T00:00:23', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '6bcc7426-57ed-4fd3-b181-0bbf05acf453' User entered 'None (0)'	System	28 Aug 2020 04:00:41
	System	28 Aug 2020 04:00:41

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-28T00:00:28', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '6bcc7426-57ed-4fd3-b181-0bbf05acf453'	System	28 Aug 2020 04:00:41
User entered 'No (N)'	System	28 Aug 2020 04:00:41

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-28T00:00:32', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '6bcc7426-57ed-4fd3-b181-0bbf05acf453' User entered '28 Aug 2020 00:00'	System	28 Aug 2020 04:00:41
	System	28 Aug 2020 04:00:41

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:55:12
User entered 'Day 5'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-28T19:44:25', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'da8bbcc5-d623-4016-ba73-f88a526f0312' User entered 'None (0)'	System	28 Aug 2020 23:44:44
	System	28 Aug 2020 23:44:44

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-28T19:44:27', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'da8bbcc5-d623-4016-ba73-f88a526f0312' User entered 'None (0)'	System	28 Aug 2020 23:44:44
	System	28 Aug 2020 23:44:44

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-28T19:44:29', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'da8bbcc5-d623-4016-ba73-f88a526f0312' User entered 'None (0)'	System	28 Aug 2020 23:44:44
	System	28 Aug 2020 23:44:44

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-28T19:44:31', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'da8bbcc5-d623-4016-ba73-f88a526f0312' User entered 'None (0)'	System	28 Aug 2020 23:44:44
	System	28 Aug 2020 23:44:44

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-28T19:44:34', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'da8bbcc5-d623-4016-ba73-f88a526f0312' User entered 'None (0)'	System	28 Aug 2020 23:44:44
	System	28 Aug 2020 23:44:44

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-28T19:44:36', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'da8bbcc5-d623-4016-ba73-f88a526f0312' User entered 'None (0)'	System	28 Aug 2020 23:44:44
	System	28 Aug 2020 23:44:44

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-28T19:44:40', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'da8bbcc5-d623-4016-ba73-f88a526f0312'	System	28 Aug 2020 23:44:44
User entered 'No (N)'	System	28 Aug 2020 23:44:44

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-28T19:44:42', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'da8bbcc5-d623-4016-ba73-f88a526f0312' User entered '28 Aug 2020 19:44'	System	28 Aug 2020 23:44:44
	System	28 Aug 2020 23:44:44

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:55:12
User entered 'Day 6'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-29T17:57:16', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '643ec5bc-52ef-45fc-b00d-78db0271d99f' User entered 'None (0)'	System	29 Aug 2020 21:57:45
	System	29 Aug 2020 21:57:45

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-29T17:57:19', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '643ec5bc-52ef-45fc-b00d-78db0271d99f' User entered 'None (0)'	System	29 Aug 2020 21:57:45
	System	29 Aug 2020 21:57:45

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-29T17:57:22', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '643ec5bc-52ef-45fc-b00d-78db0271d99f' User entered 'None (0)'	System	29 Aug 2020 21:57:45
	System	29 Aug 2020 21:57:45

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-29T17:57:25', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '643ec5bc-52ef-45fc-b00d-78db0271d99f' User entered 'None (0)'	System	29 Aug 2020 21:57:45
	System	29 Aug 2020 21:57:45

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-29T17:57:29', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '643ec5bc-52ef-45fc-b00d-78db0271d99f' User entered 'None (0)'	System	29 Aug 2020 21:57:45
	System	29 Aug 2020 21:57:45

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-29T17:57:31', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '643ec5bc-52ef-45fc-b00d-78db0271d99f' User entered 'None (0)'	System	29 Aug 2020 21:57:45
	System	29 Aug 2020 21:57:45

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-29T17:57:35', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '643ec5bc-52ef-45fc-b00d-78db0271d99f' User entered 'No (N)'	System	29 Aug 2020 21:57:45
	System	29 Aug 2020 21:57:45

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-29T17:57:39', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '643ec5bc-52ef-45fc-b00d-78db0271d99f' User entered '29 Aug 2020 17:57'	System	29 Aug 2020 21:57:45
	System	29 Aug 2020 21:57:45

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:55:12
User entered 'Day 7'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-30T14:02:07', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '5d424acc-8468-4399-8090-2d8b4574974f' User entered 'None (0)'	System	30 Aug 2020 18:02:49
	System	30 Aug 2020 18:02:49

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-30T14:02:12', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '5d424acc-8468-4399-8090-2d8b4574974f' User entered 'None (0)'	System	30 Aug 2020 18:02:49
	System	30 Aug 2020 18:02:49

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-30T14:02:17', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '5d424acc-8468-4399-8090-2d8b4574974f' User entered 'None (0)'	System	30 Aug 2020 18:02:49
	System	30 Aug 2020 18:02:49

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-30T14:02:22', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '5d424acc-8468-4399-8090-2d8b4574974f' User entered 'None (0)'	System	30 Aug 2020 18:02:49
	System	30 Aug 2020 18:02:49

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-30T14:02:26', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '5d424acc-8468-4399-8090-2d8b4574974f' User entered 'None (0)'	System	30 Aug 2020 18:02:49
	System	30 Aug 2020 18:02:49

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-30T14:02:30', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '5d424acc-8468-4399-8090-2d8b4574974f' User entered 'None (0)'	System	30 Aug 2020 18:02:49
	System	30 Aug 2020 18:02:49

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-30T14:02:42', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '5d424acc-8468-4399-8090-2d8b4574974f' User entered 'No (N)'	System	30 Aug 2020 18:02:49
	System	30 Aug 2020 18:02:49

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1573D7F4-8F90-4056-BBA6-8DDD7FAA0631)', Time: '2020-08-30T14:02:46', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '5d424acc-8468-4399-8090-2d8b4574974f' User entered '30 Aug 2020 14:02'	System	30 Aug 2020 18:02:49
	System	30 Aug 2020 18:02:49

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 19:55:12

US3372228

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 19:55:12

US3372228

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 02:35:54
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	07 Sep 2020 15:52:53

US3372228

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 02:35:54
User entered '31 Aug 2020'	Alexandra Arango (b) (4) (b) (4)	07 Sep 2020 15:52:53

US3372228

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 02:35:54
User entered 'Contact Made (CONTACT MADE)'	Alexandra Arango (b) (4) (b) (4)	07 Sep 2020 15:52:53

US3372228

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 02:35:54
User entered empty.	Alexandra Arango (b) (4) (b) (4)	07 Sep 2020 15:52:53

US3372228

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	16 Feb 2021 18:42:05
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	07 Sep 2020 15:52:57

US3372228

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '1'	System	07 Sep 2020 15:52:57

US3372228

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 02:35:54
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	07 Sep 2020 15:53:19

US3372228

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:35:54
User entered '7 Sep 2020'	(b) (4) Alexandra Arango (b) (4)	07 Sep 2020 15:53:19

US3372228

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 02:35:54
User entered 'Contact Made (CONTACT MADE)'	Alexandra Arango (b) (4) (b) (4)	07 Sep 2020 15:53:19

US3372228

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 02:35:54
User entered empty.	Alexandra Arango (b) (4) (b) (4)	07 Sep 2020 15:53:19

US3372228

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	16 Feb 2021 18:42:05
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	07 Sep 2020 15:53:28

US3372228

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '1'	System	07 Sep 2020 15:53:28

US3372228

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 02:35:54
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	14 Sep 2020 21:18:35

US3372228

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 02:35:54
User entered '14 Sep 2020'	Alexandra Arango (b) (4) (b) (4)	14 Sep 2020 21:18:35

US3372228

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 02:35:54
User entered 'Contact Made (CONTACT MADE)'	Alexandra Arango (b) (4) (b) (4)	14 Sep 2020 21:18:35

US3372228

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 02:35:54
User entered empty.	Alexandra Arango (b) (4) (b) (4)	14 Sep 2020 21:18:35

US3372228

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User signature succeeded.	Mira Baron (b) (4) (b) (4)	16 Feb 2021 18:42:05
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	14 Sep 2020 21:18:40

US3372228

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:30
User entered '1'	System	14 Sep 2020 21:18:40

US3372228

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:29
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28SEP2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:18:48
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28SEP2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	16 Nov 2020 21:40:50
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28SEP2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 12:39:08
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	28 Sep 2020 12:52:40

US3372228

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:29
User entered '28 Sep 2020'	(b) (4) Mary Sergalis (b) (4)	28 Sep 2020 12:52:40

US3372228

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

[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 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:29
User entered 'Clinic (Clinic)'	(b) (4) Mary Sergalis (b) (4)	28 Sep 2020 12:52:40

US3372228

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User entered 'VISIT2'	System	28 Sep 2020 12:52:40

US3372228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User accepted default value 'Pre-Dose (PREDOSE)'	Peter Jacob (b) (4) (b) (4)	05 Nov 2020 15:46:56

US3372228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:29
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:46:56

US3372228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:29
User entered '28 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Nov 2020 15:46:56

US3372228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:29
User entered '08:33'	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Nov 2020 15:46:56

US3372228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User entered '28 Sep 2020 08:33'	System	05 Nov 2020 15:46:56

US3372228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:29
User entered '36.4' C	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Nov 2020 15:46:56

US3372228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:29
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:46:56

US3372228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:29
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:46:56

US3372228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:29
User entered '71'	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Nov 2020 15:46:56

US3372228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User entered 'bpm'	System	05 Nov 2020 15:46:56

US3372228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:29
User entered '19'	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Nov 2020 15:46:56

US3372228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User entered 'breaths/min'	System	05 Nov 2020 15:46:56

US3372228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:29
User entered '125'	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Nov 2020 15:46:56

US3372228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User entered 'mmHg'	System	05 Nov 2020 15:46:56

US3372228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:29
User entered '73'	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Nov 2020 15:46:56

US3372228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User entered 'mmHg'	System	05 Nov 2020 15:46:56

US3372228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User accepted default value 'Post-Dose (POSTDOSE)'	Peter Jacob (b) (4) (b) (4)	05 Nov 2020 15:48:22

US3372228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:29
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Nov 2020 15:48:22

US3372228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:29
User entered '28 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Nov 2020 15:48:22

US3372228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:29
User entered '09:54'	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Nov 2020 15:48:22

US3372228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User entered '28 Sep 2020 09:54'	System	05 Nov 2020 15:48:22

US3372228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:29
User entered '36.1' C	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Nov 2020 15:48:22

US3372228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:29
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Nov 2020 15:48:22

US3372228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:29
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:48:22

US3372228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:29
User entered '68'	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Nov 2020 15:48:22

US3372228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User entered 'bpm'	System	05 Nov 2020 15:48:22

US3372228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:29
User entered '20'	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Nov 2020 15:48:22

US3372228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User entered 'breaths/min'	System	05 Nov 2020 15:48:22

US3372228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:29
User entered '119'	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Nov 2020 15:48:22

US3372228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User entered 'mmHg'	System	05 Nov 2020 15:48:22

US3372228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:29
User entered '72'	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Nov 2020 15:48:22

US3372228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User entered 'mmHg'	System	05 Nov 2020 15:48:22

US3372228

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:29
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Nov 2020 15:48:26

US3372228

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:29
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:48:26

US3372228

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:29
User entered 'Yes (Y)'	(b) (4) Mary Sergalis (b) (4)	28 Sep 2020 13:56:22

US3372228

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:29
User entered empty.	(b) (4) Mary Sergalis (b) (4)	28 Sep 2020 13:56:22

US3372228

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

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)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:29
User entered empty.	(b) (4) Mary Sergalis (b) (4)	28 Sep 2020 13:56:22

US3372228

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User entered 'MRNA-1273 OR PLACEBO'	System	28 Sep 2020 13:56:22

US3372228

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:29
User entered '28 Sep 2020'	(b) (4) Mary Sergalis (b) (4)	28 Sep 2020 13:56:22

US3372228

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:29
User entered '09:22'	(b) (4) Mary Sergalis (b) (4)	28 Sep 2020 13:56:22

US3372228

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User entered '28 Sep 2020 09:22'	System	28 Sep 2020 13:56:22

US3372228

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:29
User entered 'Left Arm (LEFT ARM)'	(b) (4) Mary Sergalis (b) (4)	28 Sep 2020 13:56:22

US3372228

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User entered 'ONCE'	System	28 Sep 2020 13:56:22

US3372228

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User entered 'INTRAMUSCULAR'	System	28 Sep 2020 13:56:22

US3372228

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:29
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Year of Birth (1956) recorded on this form does not match with the Year of birth (1965) reported in PPD Central lab. Please reconcile the correct date and update if confirmed. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:18:33
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Year of Birth (1956) recorded on this form does not match with the Year of birth (1965) reported in PPD Central lab. Please reconcile the correct date and update if confirmed. Else clarify, thank you.' answered with 'DCF has been filed' (Site from DM).	Peter Jacob (b) (4) (b) (4)	17 Nov 2020 21:04:48
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Year of Birth (1956) recorded on this form does not match with the Year of birth (1965) reported in PPD Central lab. Please reconcile the correct date and update if confirmed. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 20:25:46
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	05 Nov 2020 15:51:19

US3372228

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:29
User entered '28 Sep 2020'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:51:19

US3372228

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:29
User entered '08:48'	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Nov 2020 15:51:19

US3372228

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User entered '28 Sep 2020 08:48'	System	05 Nov 2020 15:51:19

US3372228

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:16:55

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:19:42
User entered '28 Sep 2020'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:51:26

US3372228

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Peter Jacob (b) (4) (b) (4)	05 Nov 2020 15:51:26

US3372228

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:19:42
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:51:26

US3372228

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:19:42
User entered '08:47'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:51:26

US3372228

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User entered '28 Sep 2020 08:47'	System	05 Nov 2020 15:51:26

US3372228

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Peter Jacob (b) (4) (b) (4)	05 Nov 2020 15:51:26

US3372228

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:19:42
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:51:26

US3372228

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:19:42
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:51:26

US3372228

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User entered empty.	System	05 Nov 2020 15:51:26

US3372228

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:42:05
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	05 Oct 2020 14:53:42

US3372228

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User entered '1'	System	05 Oct 2020 14:53:42

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	28 Sep 2020 13:56:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-28T10:03:30', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'f37daaa3-65e7-470c-8bff-b1847e63698a' User entered 'Yes (Y)'	System	28 Sep 2020 14:03:47
	System	28 Sep 2020 14:03:47

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-28T10:03:37', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'f37daaa3-65e7-470c-8bff-b1847e63698a' User entered '97.0'	System	28 Sep 2020 14:03:47
	System	28 Sep 2020 14:03:47

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-28T10:03:41', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'f37daaa3-65e7-470c-8bff-b1847e63698a'	System	28 Sep 2020 14:03:47
User entered 'No (N)'	System	28 Sep 2020 14:03:47

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-28T10:03:46', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'f37daaa3-65e7-470c-8bff-b1847e63698a' User entered '28 Sep 2020 10:03'	System	28 Sep 2020 14:03:47
	System	28 Sep 2020 14:03:47

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '28 Sep 2020 09:42'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '28 Sep 2020 12:12'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	28 Sep 2020 13:56:22
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-28T22:04:59', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'a64560e8-d97b-4458-8551-e84eca91322a' User entered 'Yes (Y)'	System	29 Sep 2020 02:05:17
	System	29 Sep 2020 02:05:17

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-28T22:05:05', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'a64560e8-d97b-4458-8551-e84eca91322a' User entered '97.5'	System	29 Sep 2020 02:05:17
	System	29 Sep 2020 02:05:17

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-28T22:05:09', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'a64560e8-d97b-4458-8551-e84eca91322a' User entered 'No (N)'	System	29 Sep 2020 02:05:17
	System	29 Sep 2020 02:05:17

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-28T22:05:14', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'a64560e8-d97b-4458-8551-e84eca91322a' User entered '28 Sep 2020 22:05'	System	29 Sep 2020 02:05:17
	System	29 Sep 2020 02:05:17

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '28 Sep 2020 13:07'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	28 Sep 2020 13:56:22
User entered 'Day 2'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:16:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-29T12:00:30', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'f8ccaf64-9286-471d-92cb-29d13dc8e3ed' User entered 'Yes (Y)'	System	29 Sep 2020 16:01:13
	System	29 Sep 2020 16:01:13

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:16:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-29T12:00:36', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'f8ccaf64-9286-471d-92cb-29d13dc8e3ed' User entered '97.6'	System	29 Sep 2020 16:01:13
	System	29 Sep 2020 16:01:13

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-29T12:00:49', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'f8ccaf64-9286-471d-92cb-29d13dc8e3ed' User entered 'No (N)'	System	29 Sep 2020 16:01:13
	System	29 Sep 2020 16:01:13

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-29T12:00:52', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'f8ccaf64-9286-471d-92cb-29d13dc8e3ed' User entered '29 Sep 2020 12:00'	System	29 Sep 2020 16:01:13
	System	29 Sep 2020 16:01:13

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	28 Sep 2020 13:56:22
User entered 'Day 3'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:16:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-30T12:00:28', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '510cc2d4-c3f7-423e-bccd-bcce1060620d' User entered 'Yes (Y)'	System	30 Sep 2020 16:00:58
	System	30 Sep 2020 16:00:58

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:16:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-30T12:00:34', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '510cc2d4-c3f7-423e-bccd-bcce1060620d' User entered '97.0'	System	30 Sep 2020 16:00:58
	System	30 Sep 2020 16:00:58

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-30T12:00:38', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '510cc2d4-c3f7-423e-bccd-bcce1060620d' User entered 'No (N)'	System	30 Sep 2020 16:00:58
	System	30 Sep 2020 16:00:58

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-30T12:00:43', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '510cc2d4-c3f7-423e-bccd-bcce1060620d' User entered '30 Sep 2020 12:00'	System	30 Sep 2020 16:00:58
	System	30 Sep 2020 16:00:58

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	28 Sep 2020 13:56:22
User entered 'Day 4'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:16:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:16:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:16:55

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	28 Sep 2020 13:56:22
User entered 'Day 5'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:16:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-02T23:59:28', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '3768d02e-8408-43d5-92fc-a1648daf589a' User entered 'Yes (Y)'	System	03 Oct 2020 03:59:42
	System	03 Oct 2020 03:59:42

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:16:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-02T23:59:32', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '3768d02e-8408-43d5-92fc-a1648daf589a' User entered '97.4'	System	03 Oct 2020 03:59:42
	System	03 Oct 2020 03:59:42

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-02T23:59:36', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '3768d02e-8408-43d5-92fc-a1648daf589a' User entered 'No (N)'	System	03 Oct 2020 03:59:42
	System	03 Oct 2020 03:59:42

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-02T23:59:39', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '3768d02e-8408-43d5-92fc-a1648daf589a' User entered '02 Oct 2020 23:59'	System	03 Oct 2020 03:59:42
	System	03 Oct 2020 03:59:42

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	28 Sep 2020 13:56:22
User entered 'Day 6'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:16:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-03T13:59:12', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '3a6d682b-9b49-4125-b774-b79a3b2ac076' User entered 'Yes (Y)'	System	03 Oct 2020 17:59:28
	System	03 Oct 2020 17:59:28

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:16:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-03T13:59:18', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '3a6d682b-9b49-4125-b774-b79a3b2ac076' User entered '97.6'	System	03 Oct 2020 17:59:28
	System	03 Oct 2020 17:59:28

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-03T13:59:21', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '3a6d682b-9b49-4125-b774-b79a3b2ac076'	System	03 Oct 2020 17:59:28
User entered 'No (N)'	System	03 Oct 2020 17:59:28

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-03T13:59:23', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '3a6d682b-9b49-4125-b774-b79a3b2ac076' User entered '03 Oct 2020 13:59'	System	03 Oct 2020 17:59:28
	System	03 Oct 2020 17:59:28

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	28 Sep 2020 13:56:22
User entered 'Day 7'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:16:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-04T12:00:38', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'e9a6bf6e-db13-49da-a30c-8515ce11b506' User entered 'Yes (Y)'	System	04 Oct 2020 16:01:07
	System	04 Oct 2020 16:01:07

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:16:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-04T12:00:44', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'e9a6bf6e-db13-49da-a30c-8515ce11b506' User entered '97.7'	System	04 Oct 2020 16:01:07
	System	04 Oct 2020 16:01:07

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-04T12:00:47', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'e9a6bf6e-db13-49da-a30c-8515ce11b506'	System	04 Oct 2020 16:01:07
User entered 'No (N)'	System	04 Oct 2020 16:01:07

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-04T12:00:51', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'e9a6bf6e-db13-49da-a30c-8515ce11b506' User entered '04 Oct 2020 12:00'	System	04 Oct 2020 16:01:07
	System	04 Oct 2020 16:01:07

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	28 Sep 2020 13:56:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-28T10:03:51', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '6a0a5ffa-4e91-41d1-a8a8-a53ec5eab69f'	System	28 Sep 2020 14:04:09
User entered 'None (1)'	System	28 Sep 2020 14:04:09

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-28T10:03:55', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '6a0a5ffa-4e91-41d1-a8a8-a53ec5eab69f' User entered 'No (N)'	System	28 Sep 2020 14:04:09
	System	28 Sep 2020 14:04:09

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-28T10:03:58', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '6a0a5ffa-4e91-41d1-a8a8-a53ec5eab69f' User entered 'No (N)'	System	28 Sep 2020 14:04:09
	System	28 Sep 2020 14:04:09

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-28T10:04:02', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '6a0a5ffa-4e91-41d1-a8a8-a53ec5eab69f'	System	28 Sep 2020 14:04:09
User entered 'None (1)'	System	28 Sep 2020 14:04:09

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-28T10:04:04', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '6a0a5ffa-4e91-41d1-a8a8-a53ec5eab69f' User entered '28 Sep 2020 10:04'	System	28 Sep 2020 14:04:09
	System	28 Sep 2020 14:04:09

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '28 Sep 2020 09:42'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '28 Sep 2020 12:12'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	28 Sep 2020 13:56:22
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-28T22:05:18', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '112cd2ce-4599-4dc7-aeac-71ad381d3474'	System	29 Sep 2020 02:05:41
User entered 'None (1)'	System	29 Sep 2020 02:05:41

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-28T22:05:22', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '112cd2ce-4599-4dc7-aeac-71ad381d3474' User entered 'No (N)'	System	29 Sep 2020 02:05:41
	System	29 Sep 2020 02:05:41

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-28T22:05:25', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '112cd2ce-4599-4dc7-aeac-71ad381d3474' User entered 'No (N)'	System	29 Sep 2020 02:05:41
	System	29 Sep 2020 02:05:41

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-28T22:05:28', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '112cd2ce-4599-4dc7-aeac-71ad381d3474'	System	29 Sep 2020 02:05:41
User entered 'None (1)'	System	29 Sep 2020 02:05:41

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-28T22:05:38', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '112cd2ce-4599-4dc7-aeac-71ad381d3474' User entered '28 Sep 2020 22:05'	System	29 Sep 2020 02:05:41
	System	29 Sep 2020 02:05:41

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '28 Sep 2020 13:07'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	28 Sep 2020 13:56:22
User entered 'Day 2'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:16:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-29T12:01:00', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '500c673f-cbb2-4645-a494-fc3a9be68b1f'	System	29 Sep 2020 16:02:08
User entered 'None (1)'	System	29 Sep 2020 16:02:08

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-29T12:01:09', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '500c673f-cbb2-4645-a494-fc3a9be68b1f' User entered 'No (N)'	System	29 Sep 2020 16:02:08
	System	29 Sep 2020 16:02:08

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-29T12:01:14', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '500c673f-cbb2-4645-a494-fc3a9be68b1f' User entered 'No (N)'	System	29 Sep 2020 16:02:08
	System	29 Sep 2020 16:02:08

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:16:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-29T12:01:21', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '500c673f-cbb2-4645-a494-fc3a9be68b1f'	System	29 Sep 2020 16:02:08
User entered 'None (1)'	System	29 Sep 2020 16:02:08

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-29T12:01:23', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '500c673f-cbb2-4645-a494-fc3a9be68b1f' User entered '29 Sep 2020 12:01'	System	29 Sep 2020 16:02:08
	System	29 Sep 2020 16:02:08

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	28 Sep 2020 13:56:22
User entered 'Day 3'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:16:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-30T12:00:47', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '633cc1dd-3d49-4ba3-8dd5-6ab9e148f4a7'	System	30 Sep 2020 16:01:29
User entered 'None (1)'	System	30 Sep 2020 16:01:29

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-30T12:00:51', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '633cc1dd-3d49-4ba3-8dd5-6ab9e148f4a7'	System	30 Sep 2020 16:01:29
User entered 'No (N)'	System	30 Sep 2020 16:01:29

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-30T12:00:54', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '633cc1dd-3d49-4ba3-8dd5-6ab9e148f4a7'	System	30 Sep 2020 16:01:29
User entered 'No (N)'	System	30 Sep 2020 16:01:29

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:16:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-30T12:00:58', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '633cc1dd-3d49-4ba3-8dd5-6ab9e148f4a7'	System	30 Sep 2020 16:01:29
User entered 'None (1)'	System	30 Sep 2020 16:01:29

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-30T12:01:01', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '633cc1dd-3d49-4ba3-8dd5-6ab9e148f4a7'	System	30 Sep 2020 16:01:29
User entered '30 Sep 2020 12:01'	System	30 Sep 2020 16:01:29

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	28 Sep 2020 13:56:22
User entered 'Day 4'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:16:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:16:55

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:16:55

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:16:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	28 Sep 2020 13:56:22
User entered 'Day 5'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:16:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-02T23:59:45', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'a9ddbc94-1a6a-4242-8a6b-7e8d8d3109c3'	System	03 Oct 2020 03:59:58
User entered 'None (1)'	System	03 Oct 2020 03:59:58

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-02T23:59:48', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'a9ddbc94-1a6a-4242-8a6b-7e8d8d3109c3' User entered 'No (N)'	System	03 Oct 2020 03:59:58
	System	03 Oct 2020 03:59:58

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-02T23:59:50', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'a9ddbc94-1a6a-4242-8a6b-7e8d8d3109c3' User entered 'No (N)'	System	03 Oct 2020 03:59:58
	System	03 Oct 2020 03:59:58

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:16:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-02T23:59:53', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'a9ddbc94-1a6a-4242-8a6b-7e8d8d3109c3'	System	03 Oct 2020 03:59:58
User entered 'None (1)'	System	03 Oct 2020 03:59:58

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-02T23:59:55', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'a9ddbc94-1a6a-4242-8a6b-7e8d8d3109c3' User entered '02 Oct 2020 23:59'	System	03 Oct 2020 03:59:58
	System	03 Oct 2020 03:59:58

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	28 Sep 2020 13:56:22
User entered 'Day 6'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:16:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-03T13:59:27', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '58349083-0c24-4323-beb8-4a5c394d610a' User entered 'None (1)'	System	03 Oct 2020 17:59:39
	System	03 Oct 2020 17:59:39

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-03T13:59:30', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '58349083-0c24-4323-beb8-4a5c394d610a' User entered 'No (N)'	System	03 Oct 2020 17:59:39
	System	03 Oct 2020 17:59:39

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-03T13:59:33', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '58349083-0c24-4323-beb8-4a5c394d610a' User entered 'No (N)'	System	03 Oct 2020 17:59:39
	System	03 Oct 2020 17:59:39

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:16:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-03T13:59:35', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '58349083-0c24-4323-beb8-4a5c394d610a'	System	03 Oct 2020 17:59:39
User entered 'None (1)'	System	03 Oct 2020 17:59:39

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-03T13:59:37', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '58349083-0c24-4323-beb8-4a5c394d610a' User entered '03 Oct 2020 13:59'	System	03 Oct 2020 17:59:39
	System	03 Oct 2020 17:59:39

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	28 Sep 2020 13:56:22
User entered 'Day 7'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:16:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-04T12:00:55', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'c4e39723-ca81-4b94-aeaf-7ac1cbebf2f8'	System	04 Oct 2020 16:01:26
User entered 'None (1)'	System	04 Oct 2020 16:01:26

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-04T12:00:58', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'c4e39723-ca81-4b94-aeaf-7ac1cbebf2f8'	System	04 Oct 2020 16:01:26
User entered 'No (N)'	System	04 Oct 2020 16:01:26

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-04T12:01:00', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'c4e39723-ca81-4b94-aeaf-7ac1cbebf2f8'	System	04 Oct 2020 16:01:26
User entered 'No (N)'	System	04 Oct 2020 16:01:26

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:16:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-04T12:01:03', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'c4e39723-ca81-4b94-aeaf-7ac1cbebf2f8'	System	04 Oct 2020 16:01:26
User entered 'None (1)'	System	04 Oct 2020 16:01:26

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-04T12:01:05', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'c4e39723-ca81-4b94-aeaf-7ac1cbebf2f8' User entered '04 Oct 2020 12:01'	System	04 Oct 2020 16:01:26
	System	04 Oct 2020 16:01:26

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	28 Sep 2020 13:56:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-28T10:04:10', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'cdec71e1-e351-4672-be5a-3c4a565f6595' User entered 'None (0)'	System	28 Sep 2020 14:04:44
	System	28 Sep 2020 14:04:44

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-28T10:04:12', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'cdec71e1-e351-4672-be5a-3c4a565f6595' User entered 'None (0)'	System	28 Sep 2020 14:04:44
	System	28 Sep 2020 14:04:44

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-28T10:04:15', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'cdec71e1-e351-4672-be5a-3c4a565f6595' User entered 'None (0)'	System	28 Sep 2020 14:04:44
	System	28 Sep 2020 14:04:44

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-28T10:04:18', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'cdec71e1-e351-4672-be5a-3c4a565f6595' User entered 'None (0)'	System	28 Sep 2020 14:04:44
	System	28 Sep 2020 14:04:44

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-28T10:04:21', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'cdec71e1-e351-4672-be5a-3c4a565f6595'	System	28 Sep 2020 14:04:44
User entered 'None (0)'	System	28 Sep 2020 14:04:44

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-28T10:04:24', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'cdec71e1-e351-4672-be5a-3c4a565f6595' User entered 'None (0)'	System	28 Sep 2020 14:04:44
	System	28 Sep 2020 14:04:44

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-28T10:04:32', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'cdec71e1-e351-4672-be5a-3c4a565f6595'	System	28 Sep 2020 14:04:44
User entered 'No (N)'	System	28 Sep 2020 14:04:44

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-28T10:04:37', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'cdec71e1-e351-4672-be5a-3c4a565f6595' User entered '28 Sep 2020 10:04'	System	28 Sep 2020 14:04:44
	System	28 Sep 2020 14:04:44

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '28 Sep 2020 09:42'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '28 Sep 2020 12:12'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	28 Sep 2020 13:56:22
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-28T22:05:42', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '1392170f-eb48-4111-8bad-ad64aaf6a5de' User entered 'None (0)'	System	29 Sep 2020 02:06:03
	System	29 Sep 2020 02:06:03

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-28T22:05:44', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '1392170f-eb48-4111-8bad-ad64aaf6a5de' User entered 'None (0)'	System	29 Sep 2020 02:06:03
	System	29 Sep 2020 02:06:03

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-28T22:05:47', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '1392170f-eb48-4111-8bad-ad64aaf6a5de' User entered 'None (0)'	System	29 Sep 2020 02:06:03
	System	29 Sep 2020 02:06:03

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-28T22:05:49', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '1392170f-eb48-4111-8bad-ad64aaf6a5de' User entered 'None (0)'	System	29 Sep 2020 02:06:03
	System	29 Sep 2020 02:06:03

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-28T22:05:53', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '1392170f-eb48-4111-8bad-ad64aaf6a5de' User entered 'None (0)'	System	29 Sep 2020 02:06:03
	System	29 Sep 2020 02:06:03

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-28T22:05:55', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '1392170f-eb48-4111-8bad-ad64aaf6a5de' User entered 'None (0)'	System	29 Sep 2020 02:06:03
	System	29 Sep 2020 02:06:03

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-28T22:05:58', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '1392170f-eb48-4111-8bad-ad64aaf6a5de' User entered 'No (N)'	System	29 Sep 2020 02:06:03
	System	29 Sep 2020 02:06:03

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-28T22:06:00', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '1392170f-eb48-4111-8bad-ad64aaf6a5de' User entered '28 Sep 2020 22:06'	System	29 Sep 2020 02:06:03
	System	29 Sep 2020 02:06:03

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '28 Sep 2020 13:07'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	28 Sep 2020 13:56:22
User entered 'Day 2'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-29T12:01:32', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'f91cec18-a727-4263-bfa1-279f91abf21a' User entered 'None (0)'	System	29 Sep 2020 16:02:53
	System	29 Sep 2020 16:02:53

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-29T12:01:36', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'f91cec18-a727-4263-bfa1-279f91abf21a' User entered 'None (0)'	System	29 Sep 2020 16:02:53
	System	29 Sep 2020 16:02:53

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-29T12:01:40', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'f91cec18-a727-4263-bfa1-279f91abf21a' User entered 'None (0)'	System	29 Sep 2020 16:02:53
	System	29 Sep 2020 16:02:53

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-29T12:01:45', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'f91cec18-a727-4263-bfa1-279f91abf21a' User entered 'None (0)'	System	29 Sep 2020 16:02:53
	System	29 Sep 2020 16:02:53

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-29T12:01:48', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'f91cec18-a727-4263-bfa1-279f91abf21a' User entered 'None (0)'	System	29 Sep 2020 16:02:53
	System	29 Sep 2020 16:02:53

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-29T12:01:52', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'f91cec18-a727-4263-bfa1-279f91abf21a' User entered 'None (0)'	System	29 Sep 2020 16:02:53
	System	29 Sep 2020 16:02:53

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-29T12:01:59', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'f91cec18-a727-4263-bfa1-279f91abf21a' User entered 'No (N)'	System	29 Sep 2020 16:02:53
	System	29 Sep 2020 16:02:53

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-29T12:02:02', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'f91cec18-a727-4263-bfa1-279f91abf21a' User entered '29 Sep 2020 12:02'	System	29 Sep 2020 16:02:53
	System	29 Sep 2020 16:02:53

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	28 Sep 2020 13:56:22
User entered 'Day 3'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-30T12:01:05', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '0f869c87-924e-426d-8ce6-f8451b19161f' User entered 'None (0)'	System	30 Sep 2020 16:02:13
	System	30 Sep 2020 16:02:13

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-30T12:01:07', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '0f869c87-924e-426d-8ce6-f8451b19161f' User entered 'None (0)'	System	30 Sep 2020 16:02:13
	System	30 Sep 2020 16:02:13

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-30T12:01:10', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '0f869c87-924e-426d-8ce6-f8451b19161f' User entered 'None (0)'	System	30 Sep 2020 16:02:13
	System	30 Sep 2020 16:02:13

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-30T12:01:12', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '0f869c87-924e-426d-8ce6-f8451b19161f' User entered 'None (0)'	System	30 Sep 2020 16:02:13
	System	30 Sep 2020 16:02:13

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-30T12:01:15', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '0f869c87-924e-426d-8ce6-f8451b19161f' User entered 'None (0)'	System	30 Sep 2020 16:02:13
	System	30 Sep 2020 16:02:13

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-30T12:01:17', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '0f869c87-924e-426d-8ce6-f8451b19161f' User entered 'None (0)'	System	30 Sep 2020 16:02:13
	System	30 Sep 2020 16:02:13

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-30T12:01:21', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '0f869c87-924e-426d-8ce6-f8451b19161f' User entered 'No (N)'	System	30 Sep 2020 16:02:13
	System	30 Sep 2020 16:02:13

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-09-30T12:01:25', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '0f869c87-924e-426d-8ce6-f8451b19161f' User entered '30 Sep 2020 12:01'	System	30 Sep 2020 16:02:13
	System	30 Sep 2020 16:02:13

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	28 Sep 2020 13:56:22
User entered 'Day 4'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	28 Sep 2020 13:56:22
User entered 'Day 5'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-02T23:59:59', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'c3bb64f7-ec92-45ee-a181-a5931180362e' User entered 'None (0)'	System	03 Oct 2020 04:00:18
	System	03 Oct 2020 04:00:18

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-03T00:00:01', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'c3bb64f7-ec92-45ee-a181-a5931180362e' User entered 'None (0)'	System	03 Oct 2020 04:00:18
	System	03 Oct 2020 04:00:18

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-03T00:00:03', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'c3bb64f7-ec92-45ee-a181-a5931180362e' User entered 'None (0)'	System	03 Oct 2020 04:00:18
	System	03 Oct 2020 04:00:18

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-03T00:00:05', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'c3bb64f7-ec92-45ee-a181-a5931180362e' User entered 'None (0)'	System	03 Oct 2020 04:00:18
	System	03 Oct 2020 04:00:18

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-03T00:00:08', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'c3bb64f7-ec92-45ee-a181-a5931180362e' User entered 'None (0)'	System	03 Oct 2020 04:00:18
	System	03 Oct 2020 04:00:18

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-03T00:00:11', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'c3bb64f7-ec92-45ee-a181-a5931180362e' User entered 'None (0)'	System	03 Oct 2020 04:00:18
	System	03 Oct 2020 04:00:18

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-03T00:00:14', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'c3bb64f7-ec92-45ee-a181-a5931180362e' User entered 'No (N)'	System	03 Oct 2020 04:00:18
	System	03 Oct 2020 04:00:18

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-03T00:00:16', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'c3bb64f7-ec92-45ee-a181-a5931180362e' User entered '03 Oct 2020 00:00'	System	03 Oct 2020 04:00:18
	System	03 Oct 2020 04:00:18

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	28 Sep 2020 13:56:22
User entered 'Day 6'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-03T13:59:41', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '186f2691-5fd8-4e92-9733-2b50c79e70b9' User entered 'None (0)'	System	03 Oct 2020 18:00:00
	System	03 Oct 2020 18:00:00

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-03T13:59:43', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '186f2691-5fd8-4e92-9733-2b50c79e70b9' User entered 'None (0)'	System	03 Oct 2020 18:00:00
	System	03 Oct 2020 18:00:00

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-03T13:59:45', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '186f2691-5fd8-4e92-9733-2b50c79e70b9'	System	03 Oct 2020 18:00:00
User entered 'None (0)'	System	03 Oct 2020 18:00:00

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-03T13:59:46', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '186f2691-5fd8-4e92-9733-2b50c79e70b9' User entered 'None (0)'	System	03 Oct 2020 18:00:00
	System	03 Oct 2020 18:00:00

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-03T13:59:49', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '186f2691-5fd8-4e92-9733-2b50c79e70b9' User entered 'None (0)'	System	03 Oct 2020 18:00:00
	System	03 Oct 2020 18:00:00

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-03T13:59:51', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '186f2691-5fd8-4e92-9733-2b50c79e70b9' User entered 'None (0)'	System	03 Oct 2020 18:00:00
	System	03 Oct 2020 18:00:00

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-03T13:59:54', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '186f2691-5fd8-4e92-9733-2b50c79e70b9'	System	03 Oct 2020 18:00:00
User entered 'No (N)'	System	03 Oct 2020 18:00:00

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-03T13:59:56', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '186f2691-5fd8-4e92-9733-2b50c79e70b9' User entered '03 Oct 2020 13:59'	System	03 Oct 2020 18:00:00
	System	03 Oct 2020 18:00:00

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	28 Sep 2020 13:56:22
User entered 'Day 7'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-04T12:01:09', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '7fa55274-584e-41de-ac56-b58542e8b552'	System	04 Oct 2020 16:01:52
User entered 'None (0)'	System	04 Oct 2020 16:01:52

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-04T12:01:12', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '7fa55274-584e-41de-ac56-b58542e8b552'	System	04 Oct 2020 16:01:52
User entered 'None (0)'	System	04 Oct 2020 16:01:52

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-04T12:01:14', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '7fa55274-584e-41de-ac56-b58542e8b552'	System	04 Oct 2020 16:01:52
User entered 'None (0)'	System	04 Oct 2020 16:01:52

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-04T12:01:17', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '7fa55274-584e-41de-ac56-b58542e8b552'	System	04 Oct 2020 16:01:52
User entered 'None (0)'	System	04 Oct 2020 16:01:52

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-04T12:01:19', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '7fa55274-584e-41de-ac56-b58542e8b552'	System	04 Oct 2020 16:01:52
User entered 'None (0)'	System	04 Oct 2020 16:01:52

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-04T12:01:21', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '7fa55274-584e-41de-ac56-b58542e8b552'	System	04 Oct 2020 16:01:52
User entered 'None (0)'	System	04 Oct 2020 16:01:52

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-04T12:01:24', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '7fa55274-584e-41de-ac56-b58542e8b552'	System	04 Oct 2020 16:01:52
User entered 'No (N)'	System	04 Oct 2020 16:01:52

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-04T12:01:27', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '7fa55274-584e-41de-ac56-b58542e8b552' User entered '04 Oct 2020 12:01'	System	04 Oct 2020 16:01:52
	System	04 Oct 2020 16:01:52

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 13:56:22

US3372228

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 13:56:22

US3372228

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:35:54
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	05 Oct 2020 14:54:00

US3372228

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:35:54
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:17:10
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'per CRA window was based off of visit 1 date before new amendment' (Site from System).	Peter Jacob (b) (4) (b) (4)	12 Nov 2020 22:06:33
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	05 Oct 2020 14:54:00
User entered '30 Sep 2020'	Danielle Theodore (b) (4) (b) (4)	05 Oct 2020 14:54:00

US3372228

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:35:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	05 Oct 2020 14:54:00

US3372228

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:35:54
User entered empty.	(b) (4) Danielle Theodore (b) (4)	05 Oct 2020 14:54:00
	(b) (4)	

US3372228

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:42:05
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	05 Oct 2020 14:54:44

US3372228

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User entered 'I'	System	05 Oct 2020 14:54:44

US3372228

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:35:54
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	05 Oct 2020 14:55:04
	(b) (4)	

US3372228

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:35:54
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:17:17
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'per CRA window was based off of visit 1 date before new amendment' (Site from System).	Peter Jacob (b) (4) (b) (4)	12 Nov 2020 22:06:49
User entered '05 Oct 2020' reason for change: Data Entry Error	Peter Jacob (b) (4) (b) (4)	12 Nov 2020 22:06:43
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	05 Oct 2020 14:55:04
User entered '5 Oct 2020'	Danielle Theodore (b) (4) (b) (4)	05 Oct 2020 14:55:04

US3372228

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:35:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	05 Oct 2020 14:55:04
	(b) (4)	

US3372228

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:35:54
User entered empty.	(b) (4) Danielle Theodore (b) (4)	05 Oct 2020 14:55:04
	(b) (4)	

US3372228

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:42:05
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	05 Oct 2020 14:55:38

US3372228

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User entered '1'	System	05 Oct 2020 14:55:38

US3372228

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:35:54
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	12 Oct 2020 21:58:53

US3372228

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:35:54
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	16 Oct 2020 08:52:57
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Phone visit completed within window per protocol.' (Site from System).	Alexandra Arango (b) (4) (b) (4)	12 Oct 2020 21:59:05
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	12 Oct 2020 21:58:53
User entered '12 Oct 2020'	Alexandra Arango (b) (4) (b) (4)	12 Oct 2020 21:58:53

US3372228

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:35:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	12 Oct 2020 21:58:53

US3372228

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:35:54
User entered empty.	(b) (4) Alexandra Arango (b) (4)	12 Oct 2020 21:58:53

US3372228

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:42:05
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	12 Oct 2020 21:59:10

US3372228

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User entered '1'	System	12 Oct 2020 21:59:10

US3372228

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:02:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 17:30:57

US3372228

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:02:05
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 19-Oct-2020 is reported under Visit 3 Day 57 in PPD Central lab; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:37
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 19-Oct-2020 is reported under Visit 3 Day 57 in PPD Central lab; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify. ' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	05 Nov 2020 17:35:23
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 19-Oct-2020 is reported under Visit 3 Day 57 in PPD Central lab; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 09:43:28
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	20 Oct 2020 07:27:41
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'Confirmed' (Site from System).	(b) (4), (b) (6)	19 Oct 2020 17:31:30
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	19 Oct 2020 17:30:57
User entered '19 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 17:30:57

US3372228

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

[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 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:02:05
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 17:30:57

US3372228

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User entered 'VISIT3'	System	19 Oct 2020 17:30:57

US3372228

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:02:05
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 19:57:47

US3372228

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:02:05
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 19:57:47

US3372228

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:02:05
User entered empty.	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 19:57:47

US3372228

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User entered empty.	System	04 Nov 2020 19:57:47

US3372228

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:02:05
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 19:57:47

US3372228

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:02:05
User entered empty.	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 19:57:47

US3372228

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:02:05
User entered empty.	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 19:57:47

US3372228

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:02:05
User entered empty.	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 19:57:47

US3372228

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User entered empty.	System	04 Nov 2020 19:57:47

US3372228

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:02:05
User entered empty.	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 19:57:47

US3372228

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User entered empty.	System	04 Nov 2020 19:57:47

US3372228

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:02:05
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 19:57:47

US3372228

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User entered empty.	System	04 Nov 2020 19:57:47

US3372228

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:02:05
User entered empty.	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 19:57:47

US3372228

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User entered empty.	System	04 Nov 2020 19:57:47

US3372228

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38

US3372228

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38

US3372228

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:02:05
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 19:58:03

US3372228

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:02:05
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 19:58:03

US3372228

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:02:05
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Year of Birth (1956) recorded on this form does not match with the Year of birth (1965) reported in PPD Central lab. Please reconcile the correct date and update if confirmed. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Nov 2020 08:49:10
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Year of Birth (1956) recorded on this form does not match with the Year of birth (1965) reported in PPD Central lab. Please reconcile the correct date and update if confirmed. Else clarify, thank you.' answered with 'DCF has been filed' (Site from DM).	Peter Jacob (b) (4) (b) (4)	17 Nov 2020 21:41:10
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Year of Birth (1956) recorded on this form does not match with the Year of birth (1965) reported in PPD Central lab. Please reconcile the correct date and update if confirmed. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 20:26:01
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	04 Nov 2020 20:01:55

US3372228

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:02:05
User entered '19 Oct 2020'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 20:01:55

US3372228

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:02:05
User entered '12:47'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Nov 2020 20:01:55

US3372228

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User entered '19 Oct 2020 12:47'	System	04 Nov 2020 20:01:55

US3372228

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:42:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 17:31:39

US3372228

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User entered '1'	System	19 Oct 2020 17:31:39

US3372228

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:55:12
User entered 'Day 64'	System	24 Aug 2020 19:55:12

US3372228

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-26T15:55:56', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'd1527ee6-dacb-45e8-bc7d-f50c8115eb96'	System	26 Oct 2020 19:56:11
User entered 'No (N)'	System	26 Oct 2020 19:56:11

US3372228

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-26T15:56:02', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'd1527ee6-dacb-45e8-bc7d-f50c8115eb96'	System	26 Oct 2020 19:56:11
User entered 'No (N)'	System	26 Oct 2020 19:56:11

US3372228

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-26T15:56:06', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'd1527ee6-dacb-45e8-bc7d-f50c8115eb96' User entered '26 Oct 2020 15:56:06'	System	26 Oct 2020 19:56:11
	System	26 Oct 2020 19:56:11

US3372228

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:55:12
User entered '24 Oct 2020 00:01'	System	24 Aug 2020 19:55:12

US3372228

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:55:12
User entered '28 Oct 2020 23:59'	System	24 Aug 2020 19:55:12

US3372228

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:55:12
User entered 'Day 71'	System	24 Aug 2020 19:55:12

US3372228

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-31T10:00:48', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '2cfbeea3-31f5-4e70-98ee-396255e41b13'	System	31 Oct 2020 14:00:57
User entered 'No (N)'	System	31 Oct 2020 14:00:57

US3372228

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-31T10:00:51', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '2cfbeea3-31f5-4e70-98ee-396255e41b13'	System	31 Oct 2020 14:00:57
User entered 'No (N)'	System	31 Oct 2020 14:00:57

US3372228

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-10-31T10:00:54', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '2cfbeea3-31f5-4e70-98ee-396255e41b13' User entered '31 Oct 2020 10:00:54'	System	31 Oct 2020 14:00:57
	System	31 Oct 2020 14:00:57

US3372228

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:55:12
User entered '31 Oct 2020 00:01'	System	24 Aug 2020 19:55:12

US3372228

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:55:12
User entered '04 Nov 2020 23:59'	System	24 Aug 2020 19:55:12

US3372228

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:55:12
User entered 'Day 78'	System	24 Aug 2020 19:55:12

US3372228

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-11-08T09:40:43', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'bfe0f3a0-de4c-4513-b0b8-60b7a6a257ec'	System	08 Nov 2020 14:40:51
User entered 'No (N)'	System	08 Nov 2020 14:40:51

US3372228

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-11-08T09:40:46', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'bfe0f3a0-de4c-4513-b0b8-60b7a6a257ec'	System	08 Nov 2020 14:40:51
User entered 'No (N)'	System	08 Nov 2020 14:40:51

US3372228

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-11-08T09:40:49', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'bfe0f3a0-de4c-4513-b0b8-60b7a6a257ec' User entered '08 Nov 2020 09:40:49'	System	08 Nov 2020 14:40:51
	System	08 Nov 2020 14:40:51

US3372228

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:55:12
User entered '07 Nov 2020 00:01'	System	24 Aug 2020 19:55:12

US3372228

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:55:12
User entered '11 Nov 2020 23:59'	System	24 Aug 2020 19:55:12

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:49
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 01:49:49

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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)	02 May 2021 14:07:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-11-19T23:09:27', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'b25645cd-e682-4337-ac05-8715edea414c'	System	20 Nov 2020 04:09:40
User entered 'No (N)'	System	20 Nov 2020 04:09:40

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Have you been exposed to someone with 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)	02 May 2021 14:07:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-11-19T23:09:32', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'b25645cd-e682-4337-ac05-8715edea414c'	System	20 Nov 2020 04:09:40
User entered 'No (N)'	System	20 Nov 2020 04:09:40

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-11-19T23:09:36', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'b25645cd-e682-4337-ac05-8715edea414c' User entered '19 Nov 2020 23:09:36'	System	20 Nov 2020 04:09:40
	System	20 Nov 2020 04:09:40

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:49
Amendment Manager: User entered '18 Nov 2020 00:01'	System	20 Nov 2020 01:49:49

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:49
Amendment Manager: User entered '22 Nov 2020 23:59'	System	20 Nov 2020 01:49:49

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:49
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:49:49

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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)	02 May 2021 14:07:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-11-25T13:40:06', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'd68788d7-800d-40b9-8d63-7c82e707a3e9'	System	25 Nov 2020 18:40:14
User entered 'No (N)'	System	25 Nov 2020 18:40:14

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Have you been exposed to someone with 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)	02 May 2021 14:07:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-11-25T13:40:08', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'd68788d7-800d-40b9-8d63-7c82e707a3e9'	System	25 Nov 2020 18:40:14
User entered 'No (N)'	System	25 Nov 2020 18:40:14

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-11-25T13:40:11', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'd68788d7-800d-40b9-8d63-7c82e707a3e9' User entered '25 Nov 2020 13:40:11'	System	25 Nov 2020 18:40:14
	System	25 Nov 2020 18:40:14

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:49
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 01:49:49

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:49
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 01:49:49

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:49
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:49:49

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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)	02 May 2021 14:07:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-12-02T16:01:03', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '4849e470-103b-468f-862c-3c1d3ffde598'	System	02 Dec 2020 21:01:18
User entered 'No (N)'	System	02 Dec 2020 21:01:18

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Have you been exposed to someone with 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)	02 May 2021 14:07:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-12-02T16:01:10', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '4849e470-103b-468f-862c-3c1d3ffde598'	System	02 Dec 2020 21:01:18
User entered 'No (N)'	System	02 Dec 2020 21:01:18

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-12-02T16:01:14', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '4849e470-103b-468f-862c-3c1d3ffde598' User entered '02 Dec 2020 16:01:14'	System	02 Dec 2020 21:01:18
	System	02 Dec 2020 21:01:18

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:49
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 01:49:49

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:49
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 01:49:49

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:49
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:49:49

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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)	02 May 2021 14:07:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-12-09T00:01:40', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'b5a0fdde-2adb-49b5-bc97-9229a65eaad2'	System	09 Dec 2020 05:01:54
User entered 'No (N)'	System	09 Dec 2020 05:01:54

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Have you been exposed to someone with 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)	02 May 2021 14:07:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-12-09T00:01:44', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'b5a0fdde-2adb-49b5-bc97-9229a65eaad2'	System	09 Dec 2020 05:01:54
User entered 'No (N)'	System	09 Dec 2020 05:01:54

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-12-09T00:01:48', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'b5a0fdde-2adb-49b5-bc97-9229a65eaad2' User entered '09 Dec 2020 00:01:48'	System	09 Dec 2020 05:01:54
	System	09 Dec 2020 05:01:54

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:49
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 01:49:49

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:49
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 01:49:49

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:49
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:49:49

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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)	02 May 2021 14:07:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-12-16T00:01:40', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '39a4e1af-e9cb-4737-adc1-8368f08afeb5'	System	16 Dec 2020 05:01:56
User entered 'No (N)'	System	16 Dec 2020 05:01:56

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Have you been exposed to someone with 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)	02 May 2021 14:07:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-12-16T00:01:47', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '39a4e1af-e9cb-4737-adc1-8368f08afeb5'	System	16 Dec 2020 05:01:56
User entered 'No (N)'	System	16 Dec 2020 05:01:56

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-12-16T00:01:50', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '39a4e1af-e9cb-4737-adc1-8368f08afeb5' User entered '16 Dec 2020 00:01:50'	System	16 Dec 2020 05:01:56
	System	16 Dec 2020 05:01:56

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:49
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 01:49:49

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:49
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 01:49:49

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:49
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:49:49

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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)	02 May 2021 14:07:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-12-23T00:01:26', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'f4098ea7-e0dd-46ef-8a59-73b0f4cb9041'	System	23 Dec 2020 05:02:01
User entered 'No (N)'	System	23 Dec 2020 05:02:01

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Have you been exposed to someone with 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)	02 May 2021 14:07:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-12-23T00:01:40', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'f4098ea7-e0dd-46ef-8a59-73b0f4cb9041'	System	23 Dec 2020 05:02:01
User entered 'No (N)'	System	23 Dec 2020 05:02:01

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2020-12-23T00:01:43', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'f4098ea7-e0dd-46ef-8a59-73b0f4cb9041' User entered '23 Dec 2020 00:01:43'	System	23 Dec 2020 05:02:01
	System	23 Dec 2020 05:02:01

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:49
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 01:49:49

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:49
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 01:49:49

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:49
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:49:49

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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)	02 May 2021 14:07:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2021-01-01T12:58:24', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '9027f630-2a0c-4003-803d-8cc3fbfee944'	System	01 Jan 2021 17:58:35
User entered 'No (N)'	System	01 Jan 2021 17:58:35

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Have you been exposed to someone with 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)	02 May 2021 14:07:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2021-01-01T12:58:27', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '9027f630-2a0c-4003-803d-8cc3fbfee944'	System	01 Jan 2021 17:58:35
User entered 'No (N)'	System	01 Jan 2021 17:58:35

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2021-01-01T12:58:31', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '9027f630-2a0c-4003-803d-8cc3fbfee944' User entered '01 Jan 2021 12:58:31'	System	01 Jan 2021 17:58:35
	System	01 Jan 2021 17:58:35

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:49
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 01:49:49

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:49
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 01:49:49

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:49
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:49:49

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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)	02 May 2021 14:07:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2021-01-06T10:02:43', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'f3ced2a5-0b81-4594-8629-65c2fd22a706'	System	06 Jan 2021 15:02:58
User entered 'No (N)'	System	06 Jan 2021 15:02:58

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Have you been exposed to someone with 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)	02 May 2021 14:07:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2021-01-06T10:02:52', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'f3ced2a5-0b81-4594-8629-65c2fd22a706'	System	06 Jan 2021 15:02:58
User entered 'No (N)'	System	06 Jan 2021 15:02:58

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2021-01-06T10:02:54', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: 'f3ced2a5-0b81-4594-8629-65c2fd22a706' User entered '06 Jan 2021 10:02:54'	System	06 Jan 2021 15:02:58
	System	06 Jan 2021 15:02:58

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:49
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 01:49:49

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:49
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 01:49:49

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:49
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:49:49

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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)	02 May 2021 14:07:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2021-01-15T12:27:45', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '703ebaf8-b9bf-431f-8e97-5300261b6d06'	System	15 Jan 2021 17:27:53
User entered 'No (N)'	System	15 Jan 2021 17:27:53

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Have you been exposed to someone with 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)	02 May 2021 14:07:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2021-01-15T12:27:47', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '703ebaf8-b9bf-431f-8e97-5300261b6d06'	System	15 Jan 2021 17:27:53
User entered 'No (N)'	System	15 Jan 2021 17:27:53

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2021-01-15T12:27:49', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '703ebaf8-b9bf-431f-8e97-5300261b6d06' User entered '15 Jan 2021 12:27:49'	System	15 Jan 2021 17:27:53
	System	15 Jan 2021 17:27:53

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:49
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 01:49:49

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:49
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 01:49:49

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:49
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:49:49

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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)	02 May 2021 14:07:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2021-01-22T13:14:56', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '988acbba-f7d9-4e21-baf0-08a59158ae20'	System	22 Jan 2021 18:15:05
User entered 'No (N)'	System	22 Jan 2021 18:15:05

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Have you been exposed to someone with 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)	02 May 2021 14:07:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2021-01-22T13:14:59', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '988acbba-f7d9-4e21-baf0-08a59158ae20'	System	22 Jan 2021 18:15:05
User entered 'No (N)'	System	22 Jan 2021 18:15:05

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD6C0D73-3134-40F2-A4C7-8472A5AE262C)', Time: '2021-01-22T13:15:02', User OID: 'PatientReportedOutcome (US3372228)', ODM File OID: '988acbba-f7d9-4e21-baf0-08a59158ae20' User entered '22 Jan 2021 13:15:02'	System	22 Jan 2021 18:15:05
	System	22 Jan 2021 18:15:05

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:49
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 01:49:49

US3372228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:49
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 01:49:49

US3372228

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:35:54
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	23 Nov 2020 15:56:32

US3372228

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:35:54
User entered '23 Nov 2020'	(b) (4) Danielle Theodore (b) (4)	23 Nov 2020 15:56:32
	(b) (4)	

US3372228

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:35:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	23 Nov 2020 15:56:32

US3372228

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:35:54
User entered empty.	(b) (4) Danielle Theodore (b) (4)	23 Nov 2020 15:56:32
	(b) (4)	

US3372228

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:42:05
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	23 Nov 2020 15:56:39
	(b) (4)	

US3372228

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:27:38
User entered 'I'	System	23 Nov 2020 15:56:39

US3372228

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:53:01
User signature succeeded.	Mira Baron (b) (4)	29 Apr 2021 21:05:02
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	29 Apr 2021 18:58:40
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	29 Apr 2021 18:57:31
Signature has been broken.	Peter Jacob (b) (4)	29 Apr 2021 18:57:31
User entered 'No (N)' reason for change: Data Entry Error	Peter Jacob (b) (4)	29 Apr 2021 18:57:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:35:54
User entered 'Yes (Y)'	Danielle Theodore (b) (4)	27 Dec 2020 03:08:50

US3372228

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:53:01
User signature succeeded.	Mira Baron (b) (4)	29 Apr 2021 21:05:02
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	29 Apr 2021 18:58:40
User closed query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	System	29 Apr 2021 18:58:40
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	29 Apr 2021 18:58:40
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	26 Apr 2021 17:42:29
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	26 Apr 2021 17:08:03
User closed query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4)	26 Apr 2021 10:24:27
Query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'data correct as is- see EOS module' (Site from System).	(b) (4), (b) (6)	25 Apr 2021 19:10:48
User opened query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	25 Apr 2021 19:08:13

US3372228

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	System	25 Apr 2021 19:08:13
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	25 Apr 2021 19:08:13
Signature has been broken.	(b) (4), (b) (6)	25 Apr 2021 19:08:13
User entered '28 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Apr 2021 19:08:13
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:35:54
User entered '26 Dec 2020'	(b) (4) Danielle Theodore (b) (4) (b) (4)	27 Dec 2020 03:08:50

US3372228

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:53:01
User signature succeeded.	Mira Baron (b) (4)	29 Apr 2021 21:05:02
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	29 Apr 2021 18:57:31
Signature has been broken.	(b) (4), (b) (6)	25 Apr 2021 19:30:25
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Apr 2021 19:30:25
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:35:54
User entered 'Contact Made (CONTACT MADE)'	Danielle Theodore (b) (4)	27 Dec 2020 03:08:50

US3372228

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:53:01
User signature succeeded.	Mira Baron (b) (4)	29 Apr 2021 21:05:02
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	29 Apr 2021 18:57:31
User entered 'SITE WAS NOTIFIED on 28Jan2021 that the SUBJECT PASSED AWAY ON 25JAN2021' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Apr 2021 19:32:46
Signature has been broken.	(b) (4), (b) (6)	25 Apr 2021 19:30:25
User entered 'site was notified subject passed away on 25JAN2021' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Apr 2021 19:30:25
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:35:54
User entered empty.	Danielle Theodore (b) (4)	27 Dec 2020 03:08:50

US3372228

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:53:01
User signature succeeded.	Mira Baron (b) (4)	25 Apr 2021 23:04:35
Signature has been broken.	(b) (4), (b) (6)	25 Apr 2021 19:08:19
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Apr 2021 19:08:19
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:40:47
User entered 'Yes (Y)'	Danielle Theodore (b) (4)	27 Dec 2020 03:08:59

US3372228

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:53:01
User entered empty.	System	25 Apr 2021 19:08:19
User entered '1'	System	27 Dec 2020 03:08:59

US3372228

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:30:52
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	26 Apr 2021 10:28:59
User signature succeeded.	Mira Baron (b) (4)	25 Apr 2021 23:04:35
Query 'Data is required. Please complete.' answered with 'Visit was recorded in error- no data required ' (Site from System).	(b) (4) (b) (4), (b) (6)	25 Apr 2021 19:09:32
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Apr 2021 19:08:44
Signature has been broken.	(b) (4), (b) (6)	25 Apr 2021 19:08:44
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Apr 2021 19:08:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:35:54
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	28 Jan 2021 21:12:30

US3372228

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:30:52
User signature succeeded.	Mira Baron (b) (4)	25 Apr 2021 23:04:35
User closed query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	(b) (4)	25 Apr 2021 19:08:44
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	25 Apr 2021 19:08:44
Signature has been broken.	(b) (4), (b) (6)	25 Apr 2021 19:08:44
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Apr 2021 19:08:44
User opened query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	System	24 Feb 2021 18:17:03
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	24 Feb 2021 18:17:03
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:35:54
User entered '26 Jan 2021'	(b) (4) Danielle Theodore (b) (4)	28 Jan 2021 21:12:30
	(b) (4)	

US3372228

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:30:52
User signature succeeded.	Mira Baron (b) (4)	25 Apr 2021 23:04:35
Signature has been broken.	(b) (4) (b) (4), (b) (6)	25 Apr 2021 19:08:44
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Apr 2021 19:08:44
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 02:35:54
User entered 'Contact Not Made (CONTACT NOT MADE)'	Danielle Theodore (b) (4) (b) (4)	28 Jan 2021 21:12:30

US3372228

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:30:52
User signature succeeded.	Mira Baron (b) (4)	25 Apr 2021 23:04:35
Signature has been broken.	(b) (4) (b) (4), (b) (6)	25 Apr 2021 19:08:44
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Apr 2021 19:08:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:35:54
User entered 'Subject passed away 1/25/2021'	(b) (4) Danielle Theodore (b) (4) (b) (4)	28 Jan 2021 21:12:30

US3372228

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:30:52
User signature succeeded.	Mira Baron (b) (4)	26 Apr 2021 13:45:15
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Apr 2021 10:29:09
Query 'Data is required. Please complete.' answered with 'Data entered in error- see EOS module' (Site from System).	(b) (4), (b) (6)	25 Apr 2021 19:13:48
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Apr 2021 19:12:51
Signature has been broken.	(b) (4), (b) (6)	25 Apr 2021 19:12:51
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Apr 2021 19:12:51
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:42:05
User entered 'No (N)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	28 Jan 2021 21:12:38

US3372228

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:30:52
User entered empty.	System	28 Jan 2021 21:12:38

US3372228

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	29 Apr 2021 13:20:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	29 Apr 2021 02:49:44
User closed query 'Per CDM: clarify if the PDV occurred. If no, please agree to remove all data so the form may be inactivated.' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 02:49:42
Query 'Data is required. Please complete.' answered with 'visit did not occur' (Site from System).	Peter Jacob (b) (4)	28 Apr 2021 23:03:36
Query 'Per CDM: clarify if the PDV occurred. If no, please agree to remove all data so the form may be inactivated.' answered with 'data updated' (Site from DM).	(b) (4)	28 Apr 2021 23:03:16
User opened query 'Data is required. Please complete.' (Site from System).	Peter Jacob (b) (4)	28 Apr 2021 23:01:52
User entered empty; reason for change Data Entry Error	System	28 Apr 2021 23:01:52
User opened query 'Per CDM: clarify if the PDV occurred. If no, please agree to remove all data so the form may be inactivated.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 03:11:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	20 Apr 2021 03:10:36
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Apr 2021 13:24:00
Signature has been broken.	(b) (4), (b) (6)	16 Apr 2021 13:24:00
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:23:52
User entered 'No (N)'	(b) (4)	02 Mar 2021 15:57:32
	Peter Jacob (b) (4)	
	(b) (4)	

US3372228

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	29 Apr 2021 13:20:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 03:10:36
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Apr 2021 13:24:00
Signature has been broken.	(b) (4), (b) (6)	16 Apr 2021 13:24:00
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:23:52
User entered empty.	(b) (4) Peter Jacob (b) (4)	02 Mar 2021 15:57:32

US3372228

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	29 Apr 2021 13:20:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 03:10:36
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Apr 2021 13:24:00
Signature has been broken.	(b) (4), (b) (6)	16 Apr 2021 13:24:00
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:23:52
User entered empty.	(b) (4) Peter Jacob (b) (4)	02 Mar 2021 15:57:32

US3372228

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	20 Apr 2021 03:10:36
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Apr 2021 13:24:00
User entered empty.	System	02 Mar 2021 15:57:32

US3372228

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:16:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	29 Apr 2021 13:20:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	29 Apr 2021 02:49:38
User closed query 'Per CDM: clarify if the PDV occurred. If no, please agree to remove all data so the form may be inactivated.' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 02:49:35
Query 'Data is required. Please complete.' answered with 'visit did not occur' (Site from System).	Peter Jacob (b) (4)	28 Apr 2021 23:03:31
Query 'Per CDM: clarify if the PDV occurred. If no, please agree to remove all data so the form may be inactivated.' answered with 'data updated' (Site from DM).	(b) (4)	28 Apr 2021 23:03:20
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Apr 2021 23:03:12
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	28 Apr 2021 23:03:12
User opened query 'Per CDM: clarify if the PDV occurred. If no, please agree to remove all data so the form may be inactivated.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 03:11:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	20 Apr 2021 03:11:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Apr 2021 13:24:06
Signature has been broken.	(b) (4), (b) (6)	16 Apr 2021 13:24:06
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:23:52
User entered 'No (N)'	(b) (4)	02 Mar 2021 15:57:35
	Peter Jacob (b) (4)	
	(b) (4)	

US3372228

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:16:55

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	29 Apr 2021 13:20:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 03:11:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Apr 2021 13:24:06
Signature has been broken.	(b) (4), (b) (6)	16 Apr 2021 13:24:06
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:23:52
User entered empty.	(b) (4) Peter Jacob (b) (4)	02 Mar 2021 15:57:35

US3372228

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:16:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	29 Apr 2021 13:20:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 03:11:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Apr 2021 13:24:06
Signature has been broken.	(b) (4), (b) (6)	16 Apr 2021 13:24:06
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:23:52
User entered empty.	(b) (4) Peter Jacob (b) (4)	02 Mar 2021 15:57:35

US3372228

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:16:55

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	20 Apr 2021 03:11:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Apr 2021 13:24:06
User entered empty.	System	02 Mar 2021 15:57:35

US3372228

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:16:55

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:46:39
User entered 'Yes (Y)'	(b) (4) Mary Sergalis (b) (4)	28 Jan 2021 20:25:32

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	21 Apr 2021 15:07:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:17:58
User entered 'USA-US056-2021-mRNA-1273-P301000005'	System	29 Jan 2021 18:17:53
User entered 'New'	(b) (4), (b) (6)	29 Jan 2021 18:17:53

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User closed query 'PV Query: Thank you for reporting the event of death. Please note that death is an outcome; please consider updating the event term to the underlying cause of death if available.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 13:46:18
User signature succeeded.	Mira Baron (b) (4)	21 Apr 2021 15:07:20
Query 'PV Query: Thank you for reporting the event of death. Please note that death is an outcome; please consider updating the event term to the underlying cause of death if available.' answered with 'unknown cause of death, no underlying cause available ' (Site from Safety).	Peter Jacob (b) (4)	21 Apr 2021 13:59:47
User opened query 'PV Query: Thank you for reporting the event of death. Please note that death is an outcome; please consider updating the event term to the underlying cause of death if available.' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 15:04:13
User closed query 'PV Query: Thank you for reporting the event of death. Please note that death is an outcome; please consider updating the event term to the underlying cause of death if available.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 15:23:04
Query 'PV Query: Thank you for reporting the event of death. Please note that death is an outcome; please consider updating the event term to the underlying cause of death if available.' answered with 'unknown cause as recorded in AE, when more information becomes available it will be updated' (Site from Safety).	Peter Jacob (b) (4)	02 Mar 2021 15:41:46
User opened query 'PV Query: Thank you for reporting the event of death. Please note that death is an outcome; please consider updating the event term to the underlying cause of death if available.' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 20:38:58
User coded data point as SOC: General disorders and administration site conditions, HLG: Fatal outcomes, HLT: Death and sudden death, PT: Death, LLT: Unknown cause of death - version MedDRA\23.0.	Coder Import (b) (4)	29 Jan 2021 18:37:22

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. Data point term sent to Coder	Coder Import (b) (4) (b) (4) System	29 Jan 2021 18:37:22  28 Jan 2021 20:36:42
User entered 'Death-Unknown Cause'	Mary Sergalis (b) (4) [REDACTED] [REDACTED]	28 Jan 2021 20:36:01

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	21 Apr 2021 15:07:20
User entered 'Yes (Y)'	(b) (4) Mary Sergalis (b) (4)	28 Jan 2021 20:36:01

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	21 Apr 2021 15:07:20
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	28 Jan 2021 20:36:01

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	21 Apr 2021 15:07:20
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	28 Jan 2021 20:36:01

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	21 Apr 2021 15:07:20
User entered '25 Jan 2021'	(b) (4) Mary Sergalis (b) (4)	28 Jan 2021 20:36:01

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	21 Apr 2021 15:07:20
User entered empty.	(b) (4) Mary Sergalis (b) (4)	28 Jan 2021 20:36:01

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered empty.	System	28 Jan 2021 20:36:01

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	21 Apr 2021 15:07:20
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	28 Jan 2021 20:36:01

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	21 Apr 2021 15:07:20
User entered '25 Jan 2021'	(b) (4) Mary Sergalis (b) (4)	28 Jan 2021 20:36:01

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	21 Apr 2021 15:07:20
User entered empty.	(b) (4) Mary Sergalis (b) (4)	28 Jan 2021 20:36:01

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered empty.	System	28 Jan 2021 20:36:01

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	21 Apr 2021 15:07:20
User entered 'Grade 4 (Grade 4)'	(b) (4) Mary Sergalis (b) (4)	28 Jan 2021 20:36:01

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	21 Apr 2021 15:07:20
User entered 'Yes (Y)'	(b) (4) Mary Sergalis (b) (4)	28 Jan 2021 20:36:01

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	21 Apr 2021 15:07:20
User closed query 'Per CDM: Subject died on 25Jan2021, however "End of Study/Study discontinuation" form is empty. Please consider completing this. Thank you!' (Site from DM).	(b) (4)	03 Mar 2021 11:45:36
Query 'Per CDM: Subject died on 25Jan2021, however "End of Study/Study discontinuation" form is empty. Please consider completing this. Thank you!' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	
User opened query 'Per CDM: Subject died on 25Jan2021, however "End of Study/Study discontinuation" form is empty. Please consider completing this. Thank you!' (Site from DM).	Peter Jacob (b) (4)	02 Mar 2021 15:42:36
User entered '1'	(b) (4)	04 Feb 2021 07:18:32
	(b) (4), (b) (6)	
	Mary Sergalis (b) (4)	28 Jan 2021 20:36:01

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	21 Apr 2021 15:07:20
User entered '0'	(b) (4) Mary Sergalis (b) (4)	28 Jan 2021 20:36:01

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	21 Apr 2021 15:07:20
User entered '0'	(b) (4) Mary Sergalis (b) (4)	28 Jan 2021 20:36:01

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	21 Apr 2021 15:07:20
User entered empty.	(b) (4) Mary Sergalis (b) (4)	28 Jan 2021 20:36:01

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	21 Apr 2021 15:07:20
User entered empty.	(b) (4) Mary Sergalis (b) (4)	28 Jan 2021 20:36:01

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	21 Apr 2021 15:07:20
User entered empty.	(b) (4) Mary Sergalis (b) (4)	28 Jan 2021 20:36:01

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	21 Apr 2021 15:07:20
User entered empty.	(b) (4) Mary Sergalis (b) (4)	28 Jan 2021 20:36:01

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	21 Apr 2021 15:07:20
User entered '0'	(b) (4) Mary Sergalis (b) (4)	28 Jan 2021 20:36:01

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	21 Apr 2021 15:07:20
User entered '0'	(b) (4) Mary Sergalis (b) (4)	28 Jan 2021 20:36:01

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	21 Apr 2021 15:07:20
User entered '0'	(b) (4) Mary Sergalis (b) (4)	28 Jan 2021 20:36:01

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	21 Apr 2021 15:07:20
User entered 'Not Related (NOT RELATED)'	(b) (4) Mary Sergalis (b) (4)	28 Jan 2021 20:36:01

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	21 Apr 2021 15:07:20
User entered 'Not Related (NOT RELATED)'	(b) (4) Mary Sergalis (b) (4)	28 Jan 2021 20:36:01

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	21 Apr 2021 15:07:20
User closed query 'PV Query: As the last dose of study drug was given on 28 Sep 2020, please update the action taken with [study drug] from none to not applicable.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:23:18
Query 'PV Query: As the last dose of study drug was given on 28 Sep 2020, please update the action taken with [study drug] from none to not applicable.' answered with 'data updated' (Site from Safety).	Peter Jacob (b) (4) (b) (4)	02 Mar 2021 15:45:47
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Peter Jacob (b) (4) (b) (4)	02 Mar 2021 15:43:00
User opened query 'PV Query: As the last dose of study drug was given on 28 Sep 2020, please update the action taken with [study drug] from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 20:39:50
User entered 'None (NONE)'	Mary Sergalis (b) (4)	28 Jan 2021 20:36:01

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	21 Apr 2021 15:07:20
User entered '1'	(b) (4) Mary Sergalis (b) (4)	28 Jan 2021 20:36:01

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	21 Apr 2021 15:07:20
User entered '0'	(b) (4) Mary Sergalis (b) (4)	28 Jan 2021 20:36:01

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	21 Apr 2021 15:07:20
User entered '0'	(b) (4) Mary Sergalis (b) (4)	28 Jan 2021 20:36:01

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	21 Apr 2021 15:07:20
User closed query 'Per DM CLR: Outcome = FATAL. Ensure this is reflected in End of Study eCRF if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 11:45:45
Query 'Per DM CLR: Outcome = FATAL. Ensure this is reflected in End of Study eCRF if applicable. Review and update. Else, clarify.' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	02 Mar 2021 15:45:41
User opened query 'Per DM CLR: Outcome = FATAL. Ensure this is reflected in End of Study eCRF if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 06:29:30
User entered 'Fatal (FATAL)'	Mary Sergalis (b) (4)	28 Jan 2021 20:36:01

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	21 Apr 2021 15:07:20
User entered empty.	(b) (4) Mary Sergalis (b) (4)	28 Jan 2021 20:36:01

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User closed query 'PV Query: Please provide/confirm the cause of death.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 13:46:26
User closed query 'PV Query: Thank you for reporting the subject was unblinded. Please provide the date of the unblinding.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 13:46:23
User closed query 'Per DM CLR: Narrative = SUBJECT HAD UNDERWENT A CERVICAL FUSION ON 20-JAN-2021 . However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 05:08:35
User signature succeeded.	Mira Baron (b) (4)	21 Apr 2021 15:07:20
Query 'Per DM CLR: Narrative = SUBJECT HAD UNDERWENT A CERVICAL FUSION ON 20-JAN-2021 . However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4)	21 Apr 2021 14:02:25
Query 'PV Query: Thank you for reporting the subject was unblinded. Please provide the date of the unblinding.' answered with '28JAN2021 subject was unblinded' (Site from Safety).	Peter Jacob (b) (4)	21 Apr 2021 14:01:48
Query 'PV Query: Please provide/confirm the cause of death.' answered with 'unknown cause of death, no autopsy was performed ' (Site from Safety).	Peter Jacob (b) (4)	21 Apr 2021 14:00:56
User opened query 'PV Query: Please provide/confirm the cause of death.' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 15:04:25
User closed query 'PV Query: Please provide/confirm the cause of death.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 15:23:11
Query 'PV Query: Please provide/confirm the cause of death.' answered with 'unknown cause' (Site from Safety).	Peter Jacob (b) (4)	02 Mar 2021 15:45:58
User opened query 'Per DM CLR: Narrative = SUBJECT HAD UNDERWENT A CERVICAL FUSION ON 20-JAN-2021 . However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 06:29:49

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Thank you for reporting the subject was unblinded. Please provide the date of the unblinding.' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 20:39:36
User opened query 'PV Query: Please provide/confirm the cause of death.' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 20:39:21
User entered 'Subjects wife contacted site to report that the subject passed away unexpectedly on 25-JAN-2021. Wife had gone to help the subject out of bed on the 25th of Jan., the subject was awake at the time then took a breath and passed away. Subject had underwent a Cervical Fusion on 20-JAN-2021 and discharged home after procedure with no complications. Cause of death is unknown and per the wife there will be no autopsy performed. Death certificate was requested from the wife when available. Subject was unblinded by the site and the subject had received placebo.'	Mary Sergalis (b) (4)	28 Jan 2021 20:36:01

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '1'	System	28 Jan 2021 20:36:01

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '1'	System	28 Jan 2021 20:36:01

US3372228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:16:55

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:46:05
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 23:23:09

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Nov 2020 15:53:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Nov 2020 15:53:20
Data point term sent to Coder	System	05 Nov 2020 15:52:46
User entered 'metformin'	Peter Jacob (b) (4)	05 Nov 2020 15:51:55

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:51:55

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'diabetes mellitus type II'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:51:55

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered '500'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:51:55

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'mg (mg)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:51:55

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:51:55
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'twice daily (BID)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:51:55

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:51:55

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:51:55
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:51:55
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'un UNK 2014'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:51:55

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Nov 2020 15:51:55

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:51:55

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:51:55

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:51:55

US3372228

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:16:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '2'	System	05 Nov 2020 15:51:55

US3372228

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:16:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '1'	System	05 Nov 2020 15:51:55

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '804 (804)'	System	05 Nov 2020 15:51:55

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: FOLIC ACID AND DERIVATIVES, PRODUCT: FOLIC ACID - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Nov 2020 15:55:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Nov 2020 15:55:20
Data point term sent to Coder	System	05 Nov 2020 15:53:47
User entered 'folic acid'	Peter Jacob (b) (4)	05 Nov 2020 15:53:02

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
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)	22 Feb 2021 06:41:34
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'data correct as is' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 18:39:23
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)	15 Feb 2021 12:43:29
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	05 Nov 2020 15:53:02

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'dietary supplement'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:53:02

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered '5'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:53:02

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'mg (mg)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:53:02

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:53:02

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:53:02

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:53:02

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:53:02
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:53:02
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'un UNK 2014'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:53:02

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered '0'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:53:02

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:53:02

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:53:02

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:53:02
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '1'	System	05 Nov 2020 15:53:02

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '1'	System	05 Nov 2020 15:53:02

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '804 (804)'	System	05 Nov 2020 15:53:02

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 15:56:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 15:56:20
Data point term sent to Coder User entered 'omeprazole'	System Peter Jacob (b) (4)	05 Nov 2020 15:55:51 05 Nov 2020 15:55:03

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:55:03

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'gastroesophageal reflux disease'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:55:03

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered '20'	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Nov 2020 15:55:03

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'mg (mg)'	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Nov 2020 15:55:03

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:55:03
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'twice daily (BID)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:55:03
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:55:03

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:55:03
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:55:03
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'un UNK 2008'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:55:03

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered '0'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:55:03

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:55:03

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:55:03

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 15:55:03

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '2'	System	05 Nov 2020 15:55:03

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '1'	System	05 Nov 2020 15:55:03

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '804 (804)'	System	05 Nov 2020 15:55:03

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Nov 2020 16:04:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:04:37
Data point term sent to Coder User entered 'lisinopril'	System Peter Jacob (b) (4) (b) (4)	05 Nov 2020 16:04:03 05 Nov 2020 16:03:31

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:03:31

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'hypertension'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:03:31

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered '10'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:03:31

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'mg (mg)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:03:31

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:03:31

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:03:31

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:03:31

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:03:31
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:03:31

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
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.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 06:42:20
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.' answered with 'data correct as is' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 18:41:15
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.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 12:44:17
User entered 'un UNK 2000'	Peter Jacob (b) (4) (b) (4)	05 Nov 2020 16:03:31

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered '0'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:03:31

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:03:31

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:03:31

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:03:31

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '1'	System	05 Nov 2020 16:03:31

US3372228

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:16:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '1'	System	05 Nov 2020 16:03:31

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '804 (804)'	System	05 Nov 2020 16:03:31

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Nov 2020 16:07:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:07:19
Data point term sent to Coder User entered 'atenolol'	System Peter Jacob (b) (4) (b) (4)	05 Nov 2020 16:06:06 05 Nov 2020 16:05:50

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:05:50

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'hypertension'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:05:50

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered '50'	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Nov 2020 16:05:50

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'mg (mg)'	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Nov 2020 16:05:50

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:05:50
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:05:50

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:05:50
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:05:50

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:05:50

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
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.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 06:41:05
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.' answered with 'data correct as is' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 18:41:31
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.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 12:43:01
User entered 'un UNK 2000'	Peter Jacob (b) (4) (b) (4)	05 Nov 2020 16:05:50

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Nov 2020 16:05:50

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:05:50

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:05:50

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:05:50

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '1'	System	05 Nov 2020 16:05:50

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '1'	System	05 Nov 2020 16:05:50

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '804 (804)'	System	05 Nov 2020 16:05:50

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 16:07:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 16:07:22
Data point term sent to Coder User entered 'amlodipine'	System Peter Jacob (b) (4)	05 Nov 2020 16:07:06 05 Nov 2020 16:06:11

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:06:11

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'hypertension'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:06:11

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered '5'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:06:11

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'mg (mg)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:06:11

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:06:11

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:06:11

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:06:11

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:06:11

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:06:11

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
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.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 06:40:42
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.' answered with 'data correct as is' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 18:41:47
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.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 12:42:47
User entered 'un UNK 2000'	Peter Jacob (b) (4) (b) (4)	05 Nov 2020 16:06:11

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered '0'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:06:11

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:06:11

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:06:11

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:06:11

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '1'	System	05 Nov 2020 16:06:11

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '1'	System	05 Nov 2020 16:06:11

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '804 (804)'	System	05 Nov 2020 16:06:11

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
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)	05 Nov 2020 16:07:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Nov 2020 16:07:21
Data point term sent to Coder User entered 'aspirin'	System Peter Jacob (b) (4)	05 Nov 2020 16:07:07 05 Nov 2020 16:06:49

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:06:49

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'cardiac prophylaxis'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:06:49

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered '81'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:06:49

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'mg (mg)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:06:49

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:06:49

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:06:49

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:06:49

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:06:49
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:06:49
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'un UNK 2014'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:06:49

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered '0'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:06:49

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:06:49

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:06:49

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:06:49

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '1'	System	05 Nov 2020 16:06:49

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '1'	System	05 Nov 2020 16:06:49

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '804 (804)'	System	05 Nov 2020 16:06:49

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Nov 2020 16:09:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Nov 2020 16:09:20
Data point term sent to Coder	System	05 Nov 2020 16:08:09
User entered 'trazadone'	Peter Jacob (b) (4)	05 Nov 2020 16:07:23

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:07:23

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'depression'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:07:23

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered '300'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:07:23

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'mg (mg)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:07:23

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:07:23
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:07:23

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Nov 2020 16:07:23

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:07:23

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:07:23
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'un UNK 1990'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:07:23

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered '0'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:07:23

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:07:23

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:07:23

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:07:23
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '1'	System	05 Nov 2020 16:07:23

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '1'	System	05 Nov 2020 16:07:23

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '804 (804)'	System	05 Nov 2020 16:07:23

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ESZOPICLONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Nov 2020 16:16:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:16:22
Data point term sent to Coder	System	05 Nov 2020 16:09:12
User entered 'eszopiclone'	Peter Jacob (b) (4) (b) (4)	05 Nov 2020 16:08:30

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:08:30

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'insomnia`	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:08:30
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered '1'	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Nov 2020 16:08:30

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'mg (mg)'	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Nov 2020 16:08:30

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:08:30

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:08:30

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:08:30

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:08:30
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:08:30
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'un UNK 1990'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:08:30

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Nov 2020 16:08:30

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:08:30

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:08:30

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:08:30

US3372228

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:16:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '1'	System	05 Nov 2020 16:08:30

US3372228

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:16:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '1'	System	05 Nov 2020 16:08:30

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '804 (804)'	System	05 Nov 2020 16:08:30

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
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)	15 Nov 2020 05:59:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Nov 2020 05:59:38
Data point term sent to Coder	System	05 Nov 2020 16:11:16
User entered 'vitamin B12 (cobalamin)'	Peter Jacob (b) (4)	05 Nov 2020 16:10:34

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:10:34

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'vitamin B12 deficiency'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:10:34

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered '650'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:10:34

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'ug (ug)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:10:34

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:10:34

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'every other day (QOD)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:10:34

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:10:34
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:10:34

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:10:34
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'un Aug 2019'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:10:34

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered '0'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:10:34

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:10:34

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:10:34

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:10:34
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '1'	System	05 Nov 2020 16:10:34

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '2'	System	05 Nov 2020 16:10:34

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '804 (804)'	System	05 Nov 2020 16:10:34

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE CIPIONATE, PRODUCTSYNONYM: TESTOSTERONE CYPIONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 16:23:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 16:23:20
Data point term sent to Coder	System	05 Nov 2020 16:22:50
User entered 'testosterone cypionate'	Peter Jacob (b) (4)	05 Nov 2020 16:22:06

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:22:06

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'male hypogonadism'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:22:06

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered '200'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:22:06

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'mg (mg)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:22:06

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:22:06
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'other (OTHER)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:22:06

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'bi-weekly'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:22:06

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:22:06

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:22:06
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'un UNK 2014'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:22:06

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered '0'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:22:06

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:22:06

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:22:06

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:22:06
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered empty.	System	05 Nov 2020 16:22:06

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered empty.	System	05 Nov 2020 16:22:06

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered empty.	System	05 Nov 2020 16:22:06

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:16:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Nov 2020 16:24:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Nov 2020 16:24:20
Data point term sent to Coder	System	05 Nov 2020 16:23:52
User entered 'vitamin D'	Peter Jacob (b) (4)	05 Nov 2020 16:23:10

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
Query 'Per DM CLR-query: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 06:50:00
User opened query 'Per DM CLR-query: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 06:49:40
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)	22 Feb 2021 06:42:35
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.' answered with 'data correct as is' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 18:44:18
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)	15 Feb 2021 12:45:25
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	05 Nov 2020 16:23:10

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'dietary supplement'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:23:10

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered '5000'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:23:10

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
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)	27 Feb 2021 05:46:49
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
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 'data correct as is' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:23:02
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)	15 Feb 2021 12:45:40
User entered 'mg (mg)'	Peter Jacob (b) (4) (b) (4)	05 Nov 2020 16:23:10

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:23:10
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:23:10

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:16:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:23:10

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:23:10

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:23:10

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'un Jan 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Nov 2020 16:23:10

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Nov 2020 16:23:10

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:23:10

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:16:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:23:10

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:23:10
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '1'	System	05 Nov 2020 16:23:10

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '1'	System	05 Nov 2020 16:23:10

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '804 (804)'	System	05 Nov 2020 16:23:10

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
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)	05 Nov 2020 16:24:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Nov 2020 16:24:21
Data point term sent to Coder User entered 'vitamin C'	System Peter Jacob (b) (4)	05 Nov 2020 16:23:53 05 Nov 2020 16:23:31

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
Query 'Per DM CLR-query: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 06:50:14
User opened query 'Per DM CLR-query: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 06:49:05
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)	22 Feb 2021 06:43:05
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.' answered with 'data correct as is' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 18:44:45
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)	15 Feb 2021 12:45:05
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	05 Nov 2020 16:23:31

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'dietary supplement'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:23:31

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered '1000'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:23:31

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'mg (mg)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:23:31

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:23:31

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:23:31

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:23:31
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:23:31

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:23:31

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'un Jan 2020'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:23:31

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered '0'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:23:31

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:23:31

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:23:31

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:23:31

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '1'	System	05 Nov 2020 16:23:31

US3372228

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:16:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '1'	System	05 Nov 2020 16:23:31

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '804 (804)'	System	05 Nov 2020 16:23:31

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:16:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN W/OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Nov 2020 07:07:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Nov 2020 07:07:48
Data point term sent to Coder	System	05 Nov 2020 16:35:17
User entered 'oxycodone/acetaminophen'	Peter Jacob (b) (4)	05 Nov 2020 16:34:52

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:34:52

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'generalized osteoarthritis'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:34:52

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 06:21:46
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' answered with 'data updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:51:57
User entered '10/325' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 18:51:45
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 12:44:42
User entered '10'	Peter Jacob (b) (4) (b) (4)	05 Nov 2020 16:34:52

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'mg (mg)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:34:52

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:34:52
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'as needed (PRN)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:34:52

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:16:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:34:52

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:34:52
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:34:52

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'un Jun 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Nov 2020 16:34:52

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Nov 2020 16:34:52

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:34:52

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:16:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:34:52

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:34:52
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered empty.	System	05 Nov 2020 16:34:52

US3372228

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:16:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered empty.	System	05 Nov 2020 16:34:52

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered empty.	System	05 Nov 2020 16:34:52

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PERTUSSIS VACCINES, PRODUCT: DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE;TETANUS VACCINE TOXOID, PRODUCTSYNONYM: DIPHTHERIA TETANUS PERTUSSIS VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 14:37:34
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 14:37:34
User signature succeeded.	Mira Baron (b) (4) (b) (4)	24 Feb 2021 20:52:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PERTUSSIS VACCINES, PRODUCT: DIPHTHERIA VACCINE;PERTUSSIS VACCINE;TETANUS VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:39:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:39:23
Data point term sent to Coder	System	05 Nov 2020 16:38:24
User entered 'diphtheria tetanus and acellular pertussis vaccine '	Peter Jacob (b) (4) (b) (4)	05 Nov 2020 16:37:49

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:37:49
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'diphtheria tetanus and acellular pertussis prophylaxis/prevention'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:37:49

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered '0.5'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:37:49

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'mL (mL)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:37:49

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:37:49
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'once (ONCE)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:37:49

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Nov 2020 16:37:49

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:37:49

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:37:49
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'un UNK 2012'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:37:49

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered '0'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:37:49
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:37:49
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'un UNK 2012'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:37:49

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:37:49
	(b) (4)	

US3372228

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:16:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered empty.	System	05 Nov 2020 16:37:49

US3372228

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:16:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered empty.	System	05 Nov 2020 16:37:49

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered empty.	System	05 Nov 2020 16:37:49

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:16:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 16:47:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 16:47:20
Data point term sent to Coder	System	05 Nov 2020 16:46:34
User entered 'pneumonia vaccine'	Peter Jacob (b) (4)	05 Nov 2020 16:45:45

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:45:45

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'pneumonia prophylaxis/prevention'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:45:45

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered '0.5'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:45:45

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'mL (mL)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:45:45

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:45:45
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'once (ONCE)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:45:45
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:16:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:45:45

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:45:45

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:45:45
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'un UNK 2015'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:45:45

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Nov 2020 16:45:45

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:45:45

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:16:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'un UNK 2015'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:45:45

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:45:45
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered empty.	System	05 Nov 2020 16:45:45

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered empty.	System	05 Nov 2020 16:45:45

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered empty.	System	05 Nov 2020 16:45:45

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Nov 2020 16:49:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Nov 2020 16:49:22
Data point term sent to Coder	System	05 Nov 2020 16:48:39
User entered 'herpes zoster vaccine'	Peter Jacob (b) (4)	05 Nov 2020 16:48:08

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:48:08

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'herpes zoster prophylaxis/prevention'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:48:08

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered '0.5'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:48:08

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'mL (mL)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:48:08
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:48:08

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'once (ONCE)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:48:08
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:48:08
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:48:08

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:48:08

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'un Jan 2019'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:48:08

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Nov 2020 16:48:08

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:48:08

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'un Jan 2019'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:48:08

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:48:08

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered empty.	System	05 Nov 2020 16:48:08

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered empty.	System	05 Nov 2020 16:48:08

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered empty.	System	05 Nov 2020 16:48:08

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:16:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Nov 2020 16:50:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Nov 2020 16:50:20
Data point term sent to Coder	System	05 Nov 2020 16:49:40
User entered 'influenza vaccine'	Peter Jacob (b) (4)	05 Nov 2020 16:48:47

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:48:47

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'influenza prophylaxis/prevention'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:48:47

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered '0.5'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:48:47

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'mL (mL)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:48:47
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:48:47
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'once (ONCE)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:48:47

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:16:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:48:47

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:48:47

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:48:47
	(b) (4)	

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'un Aug 2019'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:48:47

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered '0'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:48:47

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:48:47

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:16:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'un Aug 2019'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:48:47

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	05 Nov 2020 16:48:47

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered empty.	System	05 Nov 2020 16:48:47

US3372228

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:16:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered empty.	System	05 Nov 2020 16:48:47

US3372228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered empty.	System	05 Nov 2020 16:48:47

US3372228

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:16:55

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:23:52
Signature has been broken.	(b) (4) Peter Jacob (b) (4)	02 Mar 2021 16:23:59
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Peter Jacob (b) (4)	02 Mar 2021 16:23:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:11:34
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	04 Nov 2020 23:23:06

US3372228

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:16:55

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:23:52
User entered '20 Jan 2021'	(b) (4) Peter Jacob (b) (4)	02 Mar 2021 16:24:46

US3372228

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:16:55

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:23:52
User entered 'cervical fusion'	(b) (4) Peter Jacob (b) (4)	02 Mar 2021 16:24:46

US3372228

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:23:52
User entered 'Medical History (MH)'	(b) (4) Peter Jacob (b) (4)	02 Mar 2021 16:24:46

US3372228

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:16:55

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:23:52
User entered empty.	(b) (4) Peter Jacob (b) (4)	02 Mar 2021 16:24:46

US3372228

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:16:55

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:17
User signature succeeded.	Mira Baron (b) (4)	28 Apr 2021 01:02:58
User closed query 'Per CDM: Please confirm date since per safety call 119, site was informed of death on 28Jan2021. Please reconcile, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Apr 2021 08:36:14
Query 'Per CDM: Please confirm date since per safety call 119, site was informed of death on 28Jan2021. Please reconcile, else clarify.' answered with 'the Date of study discontinuation should be the date of death, despite the fact that the site was informed about this on 28Jan2021. The information is correct as is: 25Jan2021'.' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 17:42:55
User closed query 'Date of Study Discontinuation/Completion is after Date of Death. Please correct.' (Site from System).	System	26 Apr 2021 17:42:29
User entered '25 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Apr 2021 17:42:29
User opened query 'Date of Study Discontinuation/Completion is after Date of Death. Please correct.' (Site from System).	System	26 Apr 2021 17:08:03
Signature has been broken.	(b) (4), (b) (6)	26 Apr 2021 17:08:03
User entered '28 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Apr 2021 17:08:03
User opened query 'Per CDM: Please confirm date since per safety call 119, site was informed of death on 28Jan2021. Please reconcile, else clarify.' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 10:28:41
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:17:03

US3372228

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:16:55

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:17
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Death (DEATH)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:17:03

US3372228

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:17
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:17:03

US3372228

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:16:55

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:17
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:27
User closed query 'Per CDM: Death-Unknown Cause' is entered as an Adverse Event therefore the cause of death should be captured as Adverse Event on the study discontinuation form. Please reconcile. (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:27:05
Signature has been broken.	Peter Jacob (b) (4)	21 Apr 2021 14:03:55
User entered 'Adverse event (ADVERSE EVENT)' reason for change: Data Entry Error	(b) (4)	
Query 'Per CDM: Death-Unknown Cause' is entered as an Adverse Event therefore the cause of death should be captured as Adverse Event on the study discontinuation form. Please reconcile.' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4)	21 Apr 2021 14:03:55
User opened query 'Per CDM: Death-Unknown Cause' is entered as an Adverse Event therefore the cause of death should be captured as Adverse Event on the study discontinuation form. Please reconcile. (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 16:30:31
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'Unknown (UNKNOWN)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:17:03

US3372228

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:16:55

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:17
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:17:03

US3372228

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:16:55

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:17
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:17:03

US3372228

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:16:55

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:17
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:17:03

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered 'USA-US056-2021-MRNA-1273-P301000005'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered 'Yes (Y)'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered 'Yes (Y)'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered 'No (N)'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered 'No (N)'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered 'No (N)'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered 'No (N)'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered 'No (N)'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered 'Mira'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered 'Baron'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered '2277 Palm beach Lakes Blvd'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered 'West Palm Beach'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:27
User entered 'Florida'	(b) (4) Mary Sergalis (b) (4)	21 Apr 2021 15:10:58

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered '33409'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:23:34
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
User entered 'US'	(b) (4) System	29 Jan 2021 18:18:23

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '2'	System	03 Mar 2021 15:23:48
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
User entered '1'	(b) (4) System	29 Jan 2021 18:18:23

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered 'USA-US056-2021-MRNA-1273-P301000005'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered 'Yes (Y)'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered 'Yes (Y)'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered 'No (N)'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered 'No (N)'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered 'No (N)'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered 'No (N)'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered 'No (N)'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered 'Mira'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered 'Baron'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered '2277 Palm beach Lakes Blvd'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered 'West Palm Beach'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:27
User entered 'Florida'	(b) (4) Mary Sergalis (b) (4)	21 Apr 2021 15:10:58

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered '33409'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:23:34
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
User entered 'US'	(b) (4) System	29 Jan 2021 18:18:23

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '2'	System	03 Mar 2021 15:23:48
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
User entered '1'	(b) (4) System	29 Jan 2021 18:18:23

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:16:55

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
User entered '29/Jan/2021 13:18'	(b) (4) System	29 Jan 2021 18:18:23

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:16:55

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:23:34
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
User entered '1'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:23

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered 'USA-US056-2021-MRNA-1273-P301000005'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered 'Yes (Y)'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered 'Yes (Y)'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered 'No (N)'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered 'No (N)'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered 'No (N)'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered 'No (N)'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered 'No (N)'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered 'Mira'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered 'Baron'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered '2277 Palm beach Lakes Blvd'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered 'West Palm Beach'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:27
User entered 'Florida'	(b) (4) Mary Sergalis (b) (4)	21 Apr 2021 15:10:58

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:18:12
User entered '33409'	System	29 Jan 2021 18:17:53

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:23:34
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
User entered 'US'	(b) (4) System	29 Jan 2021 18:18:23

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User entered '2'	System	03 Mar 2021 15:23:48
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:20
User entered '1'	(b) (4) System	29 Jan 2021 18:18:23

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:16:55

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:23:52
User entered '03/Mar/2021 09:23'	(b) (4) System	03 Mar 2021 15:23:48

US3372228

Folder: SAE USA-US056-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:16:55

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:47
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:23:52
User entered '1'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:23:48