

US3292365 (Prod: Clinical Trials of Texas, Inc)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:27:54

All time stamps listed in this document are displayed in GMT

US3292365

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 14:33:43

Generated On: 09 Jun 2021 16:27:54

[Participant ID](#)

US3292365

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

US3292365

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:44:19

Generated On: 09 Jun 2021 16:27:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 23 Feb 2021 18:44:19

Generated On: 09 Jun 2021 16:27:54

Date of Birth (MMM yyyy)	(b) (6) 1962
Age	58
Age Units	YEARS
Age (Derived)	58
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 23 Feb 2021 18:44:19

Generated On: 09 Jun 2021 16:27:54

Date of Informed Consent (<i>dd MMM yyyy</i>)	29 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 23 Feb 2021 18:44:19

Generated On: 09 Jun 2021 16:27:54

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 23 Feb 2021 18:44:19

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 16 Apr 2021 14:48:57

Generated On: 09 Jun 2021 16:27:54

Condition	MOLD ALLERGY
Start date (dd MMM yyyy)	UN UNK 1984
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 1984
Start Year (derived)	1984
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 16 Apr 2021 14:48:57

Generated On: 09 Jun 2021 16:27:54

Condition	OAK ALLERGY
Start date (dd MMM yyyy)	UN UNK 1984
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 1984
Start Year (derived)	1984
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 16 Apr 2021 14:48:57

Generated On: 09 Jun 2021 16:27:54

Condition	BEE STING ALLERGY
Start date (dd MMM yyyy)	UN UNK 1981
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 1981
Start Year (derived)	1981
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 16 Apr 2021 14:48:57

Generated On: 09 Jun 2021 16:27:54

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 16 Apr 2021 14:48:57

Generated On: 09 Jun 2021 16:27:54

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 16 Apr 2021 14:48:57

Generated On: 09 Jun 2021 16:27:54

Condition	C-SECTION
Start date (dd MMM yyyy)	UN UNK 1989
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 1989
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1989
Start Year (derived)	1989
Stop Month and Year (derived)	JAN 1989
Stop Year (derived)	1989

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 16 Apr 2021 14:48:57

Generated On: 09 Jun 2021 16:27:54

Condition	LAPAROSCOPY FOR ENDOMETRIOSIS
Start date (dd MMM yyyy)	UN UNK 1997
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 1997
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1997
Start Year (derived)	1997
Stop Month and Year (derived)	JAN 1997
Stop Year (derived)	1997

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 16 Apr 2021 14:48:57

Generated On: 09 Jun 2021 16:27:54

Condition	ENDOMETRIOSIS
Start date (dd MMM yyyy)	UN UNK 1997
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 1997
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1997
Start Year (derived)	1997
Stop Month and Year (derived)	JAN 1997
Stop Year (derived)	1997

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 16 Apr 2021 14:48:57

Generated On: 09 Jun 2021 16:27:54

Condition	RIGHT EYE LASIK
Start date (dd MMM yyyy)	06 AUG 2020
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)	06 AUG 2020
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	AUG 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 16 Apr 2021 14:48:57

Generated On: 09 Jun 2021 16:27:54

Condition	COLONOSCOPY
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 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 16 Apr 2021 14:48:57

Generated On: 09 Jun 2021 16:27:54

Condition	POLYP REMOVAL
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 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 16 Apr 2021 14:48:57

Generated On: 09 Jun 2021 16:27:54

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

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 16 Apr 2021 14:48:57

Generated On: 09 Jun 2021 16:27:54

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

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 16 Apr 2021 14:48:57

Generated On: 09 Jun 2021 16:27:54

Condition	LEFT HAND AND FOOT BASAL CELL REMOVAL
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 16 Apr 2021 14:48:57

Generated On: 09 Jun 2021 16:27:54

Condition	LEFT HAND AND FOOT BASAL CELL CARCINOMA
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 16 Apr 2021 14:48:57

Generated On: 09 Jun 2021 16:27:54

Condition	BILATERAL DECREASED VISUAL ACUITY
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 16 Apr 2021 14:48:57

Generated On: 09 Jun 2021 16:27:54

Condition	CHRONIC COUGH
Start date (dd MMM yyyy)	UN UNK 1977
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 1977
Start Year (derived)	1977
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 16 Apr 2021 14:48:57

Generated On: 09 Jun 2021 16:27:54

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Start Year (derived)	1998
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 16 Apr 2021 14:48:57

Generated On: 09 Jun 2021 16:27:54

Condition	COLON POLYP BENIGN
Start date (dd MMM yyyy)	UN UNK 2012
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 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 16 Apr 2021 14:48:57

Generated On: 09 Jun 2021 16:27:54

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

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 16 Apr 2021 14:48:57

Generated On: 09 Jun 2021 16:27:54

Condition	MIGRAINES
Start date (dd MMM yyyy)	UN UNK 1993
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 1993
Start Year (derived)	1993
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 16 Apr 2021 14:48:57

Generated On: 09 Jun 2021 16:27:54

Condition	ACNE
Start date (dd MMM yyyy)	UN UNK 1970
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 1970
Start Year (derived)	1970
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 16 Apr 2021 14:48:57

Generated On: 09 Jun 2021 16:27:54

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

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Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 16 Apr 2021 14:48:57

Generated On: 09 Jun 2021 16:27:54

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

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Folder: Screening

Form: Medical History (25)

Data signed: (b) (4) 16 Apr 2021 14:48:57

Generated On: 09 Jun 2021 16:27:54

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

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Folder: Screening

Form: Medical History (26)

Data signed: (b) (4) 16 Apr 2021 14:48:57

Generated On: 09 Jun 2021 16:27:54

Condition	GENERAL ACHES
Start date (dd MMM yyyy)	UN AUG 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)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3292365

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 18:44:19

Generated On: 09 Jun 2021 16:27:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 AUG 2020
Time of assessment (00:00-23:59)	10:11 (24 HR)
Vital Signs Date and Time (derived)	29 AUG 2020 10:11
Height (xxx.x)	179.4 cm
Weight (xxx.x)	92.0 kg
BMI (xxx.x)	28.58531 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:44:19

Generated On: 09 Jun 2021 16:27:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 23 Feb 2021 18:44:19

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Date of assessment (dd MMM yyyy) 29 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

If No, what is the reason? Surgically sterile ☐
Post-menopausal ☒
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) _____

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 2014

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 18:44:19

Generated On: 09 Jun 2021 16:27:54

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

FREQUENT GROCERY STORE,
GYMS WITH HIGH CUSTOMER
VOLUME

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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EAB) (1725)

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Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 18:44:19

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:44:20

Generated On: 09 Jun 2021 16:27:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 23 Feb 2021 18:44:19

Generated On: 09 Jun 2021 16:27:54

What was the date of randomization? (dd MMM yyyy) 29 AUG 2020

What was the participant's randomization number? 109997

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 18:44:20

Generated On: 09 Jun 2021 16:27:54

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 18:44:20

Generated On: 09 Jun 2021 16:27:54

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 AUG 2020
Time of assessment (00:00-23:59)	11:21 (24 HR)
Vital Signs Date and Time (derived)	29 AUG 2020 11:21
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 18:44:20

Generated On: 09 Jun 2021 16:27:54

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 AUG 2020
Time of assessment (00:00-23:59)	13:16 (24 HR)
Vital Signs Date and Time (derived)	29 AUG 2020 13:16
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3292365

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:44:19

Generated On: 09 Jun 2021 16:27:54

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.

US3292365

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 18:44:19

Generated On: 09 Jun 2021 16:27:54

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) 29 AUG 2020

What was the treatment time? (00:00-23:59) 12:45 (24 HR)

Treatment Date and Time (derived) 29 AUG 2020 12:45

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

US3292365

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:44:19

Generated On: 09 Jun 2021 16:27:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 AUG 2020
Collection time (00:00-23:59)	11:35 (24 HR)
Collection date and time (derived)	29 AUG 2020 11:35

US3292365

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 18:44:19

Generated On: 09 Jun 2021 16:27:54

Collection date (dd MMM yyyy)			29 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:50	29 AUG 2020 11:50
Nasopharyngeal Swab 2	No		

US3292365

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:44:19

Generated On: 09 Jun 2021 16:27:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 13:22

PC Open Date & Time

29 AUG 2020 13:05

PC Close Date & Time

29 AUG 2020 15:35

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

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

97.2 °F

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

Yes ☐
No ☒

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

PC Time Stamp	29 AUG 2020 20:55
PC Open Date & Time	29 AUG 2020 16:30
PC Close Date & Time	30 AUG 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 21:33

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °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

31 AUG 2020 21:07

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 21:06

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 21:48

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 21:04

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 22:41

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

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

29 AUG 2020 13:23

PC Open Date & Time

29 AUG 2020 13:05

PC Close Date & Time

29 AUG 2020 15:35

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

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

2

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

29 AUG 2020 20:58

PC Open Date & Time

29 AUG 2020 16:30

PC Close Date & Time

30 AUG 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

2

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 21:39

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 21:07

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:54

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

01 SEP 2020 21:07

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 21:49

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 21:05

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 22:41

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

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 ☐

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

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

No ☒

Yes ☐

PC Time stamp	29 AUG 2020 13:23
PC Open Date & Time	29 AUG 2020 13:05
PC Close Date & Time	29 AUG 2020 15:35

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

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 ☐

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

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

No ☒

Yes ☐

PC Time stamp	29 AUG 2020 20:58
PC Open Date & Time	29 AUG 2020 16:30
PC Close Date & Time	30 AUG 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:54

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 21:39
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:54

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 21:07
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:54

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 21:07
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:54

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 21:49
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:54

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 21:05
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:54

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 ☒

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:54

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 22:42
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3292365

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:44:19

Generated On: 09 Jun 2021 16:27:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292365

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:44:19

Generated On: 09 Jun 2021 16:27:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292365

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:44:18

Generated On: 09 Jun 2021 16:27:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292365

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:44:18

Generated On: 09 Jun 2021 16:27:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292365

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:44:18

Generated On: 09 Jun 2021 16:27:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292365

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:44:18

Generated On: 09 Jun 2021 16:27:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292365

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:44:20

Generated On: 09 Jun 2021 16:27:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 18:44:20

Generated On: 09 Jun 2021 16:27:54

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 SEP 2020
Time of assessment (00:00-23:59)	08:45 (24 HR)
Vital Signs Date and Time (derived)	26 SEP 2020 08:45
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 18:44:20

Generated On: 09 Jun 2021 16:27:54

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 SEP 2020
Time of assessment (00:00-23:59)	10:14 (24 HR)
Vital Signs Date and Time (derived)	26 SEP 2020 10:14
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3292365

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:44:20

Generated On: 09 Jun 2021 16:27:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 SEP 2020

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

US3292365

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 18:44:20

Generated On: 09 Jun 2021 16:27:54

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 09:42 (24 HR)

Treatment Date and Time (derived) 26 SEP 2020 09:42

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

US3292365

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:44:20

Generated On: 09 Jun 2021 16:27:54

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 SEP 2020

Collection time (00:00-23:59)

08:53 (24 HR)

Collection date and time (derived)

26 SEP 2020 08:53

US3292365

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 18:44:20

Generated On: 09 Jun 2021 16:27:54

Collection date (dd MMM yyyy)			26 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:09	26 SEP 2020 09:09
Nasopharyngeal Swab 2	No		

US3292365

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:44:20

Generated On: 09 Jun 2021 16:27:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 10:17

PC Open Date & Time

26 SEP 2020 10:02

PC Close Date & Time

26 SEP 2020 12:32

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

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

96.4 °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	26 SEP 2020 21:31
PC Open Date & Time	26 SEP 2020 13:27
PC Close Date & Time	27 SEP 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

100.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 21:03

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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 20:56

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 22:31

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 22:22

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

01 OCT 2020 20:37

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °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

02 OCT 2020 23:27

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

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

26 SEP 2020 10:19

PC Open Date & Time

26 SEP 2020 10:02

PC Close Date & Time

26 SEP 2020 12:32

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

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

26 SEP 2020 21:32

PC Open Date & Time

26 SEP 2020 13:27

PC Close Date & Time

27 SEP 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

4

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)**

4

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 21:06

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

6

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 - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 21:00

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 22:32

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 22:20

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 20:38

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 23:27

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

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 ☐

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

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

No ☒

Yes ☐

PC Time stamp	26 SEP 2020 10:19
PC Open Date & Time	26 SEP 2020 10:02
PC Close Date & Time	26 SEP 2020 12:32

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

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 ☐

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

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

No ☒

Yes ☐

PC Time stamp	26 SEP 2020 21:33
PC Open Date & Time	26 SEP 2020 13:27
PC Close Date & Time	27 SEP 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:54

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 21:07
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:54

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 21:00
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:54

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 22:32
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:54

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 ☒

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EAB) (1725)

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:54

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 22:20
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:54

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 20:38
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:54

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 23:27
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3292365

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:44:19

Generated On: 09 Jun 2021 16:27:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292365

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:44:18

Generated On: 09 Jun 2021 16:27:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292365

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:44:19

Generated On: 09 Jun 2021 16:27:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292365

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:44:19

Generated On: 09 Jun 2021 16:27:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292365

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:44:19

Generated On: 09 Jun 2021 16:27:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292365

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:44:19

Generated On: 09 Jun 2021 16:27:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292365

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:44:20

Generated On: 09 Jun 2021 16:27:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3292365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 18:44:20

Generated On: 09 Jun 2021 16:27:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 OCT 2020
Time of assessment (00:00-23:59)	07:54 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 07:54
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3292365

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:44:20

Generated On: 09 Jun 2021 16:27:54

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.

US3292365

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:44:20

Generated On: 09 Jun 2021 16:27:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 OCT 2020
Collection time (00:00-23:59)	08:07 (24 HR)
Collection date and time (derived)	27 OCT 2020 08:07

US3292365

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:44:20

Generated On: 09 Jun 2021 16:27:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 OCT 2020 13:54:44

Patient Cloud Open Date & Time

29 OCT 2020 00:01

Patient Cloud Close Date & Time

02 NOV 2020 23:59

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

07 NOV 2020 16:46:40

Patient Cloud Open Date & Time

05 NOV 2020 00:01

Patient Cloud Close Date & Time

09 NOV 2020 23:59

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	14 NOV 2020 12:56:08
Patient Cloud Open Date & Time	12 NOV 2020 00:01
Patient Cloud Close Date & Time	16 NOV 2020 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	20 NOV 2020 19:07:04
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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 <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	25 NOV 2020 12:00:50
Patient Cloud Open Date & Time	23 NOV 2020 00:01
Patient Cloud Close Date & Time	27 NOV 2020 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 DEC 2020 15:56:37
Patient Cloud Open Date & Time	30 NOV 2020 00:01
Patient Cloud Close Date & Time	04 DEC 2020 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

10 DEC 2020 13:54:16

Patient Cloud Open Date & Time

07 DEC 2020 00:01

Patient Cloud Close Date & Time

11 DEC 2020 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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	17 DEC 2020 18:02:20
Patient Cloud Open Date & Time	14 DEC 2020 00:01
Patient Cloud Close Date & Time	18 DEC 2020 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

23 DEC 2020 12:01:06

Patient Cloud Open Date & Time

21 DEC 2020 00:01

Patient Cloud Close Date & Time

25 DEC 2020 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

30 DEC 2020 16:57:05

Patient Cloud Open Date & Time

28 DEC 2020 00:01

Patient Cloud Close Date & Time

01 JAN 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 JAN 2021 10:01:04

Patient Cloud Open Date & Time

04 JAN 2021 00:01

Patient Cloud Close Date & Time

08 JAN 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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	13 JAN 2021 07:19:56
Patient Cloud Open Date & Time	11 JAN 2021 00:01
Patient Cloud Close Date & Time	15 JAN 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 JAN 2021 15:41:50

Patient Cloud Open Date & Time

18 JAN 2021 00:01

Patient Cloud Close Date & Time

22 JAN 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 JAN 2021 10:41:06

Patient Cloud Open Date & Time

25 JAN 2021 00:01

Patient Cloud Close Date & Time

29 JAN 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 FEB 2021 12:05:16

Patient Cloud Open Date & Time

01 FEB 2021 00:01

Patient Cloud Close Date & Time

05 FEB 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 FEB 2021 12:02:11

Patient Cloud Open Date & Time

08 FEB 2021 00:01

Patient Cloud Close Date & Time

12 FEB 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 FEB 2021 09:09:40

Patient Cloud Open Date & Time

15 FEB 2021 00:01

Patient Cloud Close Date & Time

19 FEB 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	23 FEB 2021 08:57:20
Patient Cloud Open Date & Time	22 FEB 2021 00:01
Patient Cloud Close Date & Time	26 FEB 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAR 2021 12:01:55

Patient Cloud Open Date & Time

01 MAR 2021 00:01

Patient Cloud Close Date & Time

05 MAR 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 MAR 2021 12:09:24

Patient Cloud Open Date & Time

08 MAR 2021 00:01

Patient Cloud Close Date & Time

12 MAR 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	18 MAR 2021 11:56:40
Patient Cloud Open Date & Time	15 MAR 2021 00:01
Patient Cloud Close Date & Time	19 MAR 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 APR 2021 10:53:26

Patient Cloud Open Date & Time

29 MAR 2021 00:01

Patient Cloud Close Date & Time

02 APR 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 APR 2021 12:00:28

Patient Cloud Open Date & Time

05 APR 2021 00:01

Patient Cloud Close Date & Time

09 APR 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 APR 2021 09:59:42

Patient Cloud Open Date & Time

12 APR 2021 00:01

Patient Cloud Close Date & Time

16 APR 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 10:00:35

Patient Cloud Open Date & Time

19 APR 2021 00:01

Patient Cloud Close Date & Time

23 APR 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 APR 2021 10:00:35

Patient Cloud Open Date & Time

26 APR 2021 00:01

Patient Cloud Close Date & Time

30 APR 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

[Patient Cloud Open Date & Time](#)

03 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

07 MAY 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

[Patient Cloud Open Date & Time](#)

10 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

[Patient Cloud Open Date & Time](#)

24 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

[Patient Cloud Open Date & Time](#)

21 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 JUL 2021 00:01
Patient Cloud Close Date & Time	09 JUL 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 JUL 2021 00:01
Patient Cloud Close Date & Time	16 JUL 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUL 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

[Patient Cloud Open Date & Time](#)

26 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUL 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

[Patient Cloud Open Date & Time](#)

16 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

20 AUG 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

17 SEP 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 397
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

[Patient Cloud Open Date & Time](#)

27 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

[Patient Cloud Open Date & Time](#)

04 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

08 OCT 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

[Patient Cloud Open Date & Time](#)

18 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

22 OCT 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

Patient Cloud Open Date & Time	25 OCT 2021 00:01
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Patient Cloud Close Date & Time	29 OCT 2021 23:59
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US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

[Patient Cloud Open Date & Time](#)

15 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

19 NOV 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

[Patient Cloud Open Date & Time](#)

22 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	29 NOV 2021 00:01
Patient Cloud Close Date & Time	03 DEC 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

Patient Cloud Open Date & Time	20 DEC 2021 00:01
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Patient Cloud Close Date & Time	24 DEC 2021 23:59
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US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 DEC 2021 00:01
Patient Cloud Close Date & Time	31 DEC 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

[Patient Cloud Open Date & Time](#)

03 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

[Patient Cloud Open Date & Time](#)

17 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

[Patient Cloud Open Date & Time](#)

07 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

[Patient Cloud Open Date & Time](#)

14 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

[Patient Cloud Open Date & Time](#)

14 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

[Patient Cloud Open Date & Time](#)

21 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

[Patient Cloud Open Date & Time](#)

28 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 APR 2022 00:01
Patient Cloud Close Date & Time	15 APR 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 APR 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

[Patient Cloud Open Date & Time](#)

02 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

[Patient Cloud Open Date & Time](#)

16 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 JUL 2022 00:01
Patient Cloud Close Date & Time	15 JUL 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 AUG 2022 00:01
Patient Cloud Close Date & Time	19 AUG 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

[Patient Cloud Open Date & Time](#)

22 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 SEP 2022 00:01
Patient Cloud Close Date & Time	16 SEP 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

[Patient Cloud Open Date & Time](#)

19 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

[Patient Cloud Open Date & Time](#)

26 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

[Patient Cloud Open Date & Time](#)

03 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

[Patient Cloud Open Date & Time](#)

17 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2022 23:59

US3292365

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:27:54

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		03 MAR 2021 12:02:12

US3292365

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:44:19

Generated On: 09 Jun 2021 16:27:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292365

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:44:19

Generated On: 09 Jun 2021 16:27:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292365

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:44:18

Generated On: 09 Jun 2021 16:27:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292365

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:44:18

Generated On: 09 Jun 2021 16:27:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292365

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:44:18

Generated On: 09 Jun 2021 16:27:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292365

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:44:18

Generated On: 09 Jun 2021 16:27:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292365

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 03 Mar 2021 14:22:13

Generated On: 09 Jun 2021 16:27:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292365

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 03 Mar 2021 14:22:13

Generated On: 09 Jun 2021 16:27:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292365

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:51:55

Generated On: 09 Jun 2021 16:27:54

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

US3292365

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:51:55

Generated On: 09 Jun 2021 16:27:54

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) _____

US3292365

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:48:57

Generated On: 09 Jun 2021 16:27:54

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.

US3292365

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:48:57

Generated On: 09 Jun 2021 16:27:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 MAR 2021
Collection time (00:00-23:59)	13:47 (24 HR)
Collection date and time (derived)	22 MAR 2021 13:47

US3292365

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:48:57

Generated On: 09 Jun 2021 16:27:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292365

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

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

US3292365

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:54

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3292365

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:27:54

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"/>

US3292365

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:27:54

Generate Next COVID-19 Assessment

Yes ☐

No ☐

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:44:18

Generated On: 09 Jun 2021 16:27:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3292365

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 14:48:57

Generated On: 09 Jun 2021 16:27:54

Date of updated informed consent (dd MMM yyyy) 2 FEB 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 2 FEB 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3292365

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:44:18

Generated On: 09 Jun 2021 16:27:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 FEB 2021
Collection time (00:00-23:59)	11:12 (24 HR)
Collection date and time (derived)	2 FEB 2021 11:12

US3292365

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 18:44:18

Generated On: 09 Jun 2021 16:27:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 FEB 2021
Collection time (00:00 - 23:59)	11:30
Collection Date and Time (derived)	2 FEB 2021 11:30

US3292365

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 18:44:18

Generated On: 09 Jun 2021 16:27:54

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 20:04:29

Generated On: 09 Jun 2021 16:27:54

AEID	USA-US072-2020-MRNA-1273-P30 1000010
Adverse event	INVASIVE LOBULAR BREAST CARCINOMA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	9 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	14 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 20:04:29

Generated On: 09 Jun 2021 16:27:54

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

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 20:04:29

Generated On: 09 Jun 2021 16:27:54

PATIENT CONTACTED STUDY
STAFF THIS AFTERNOON
(09NOV2020) TO INFORM THE
STUDY TEAM THAT SHE HAD
RECEIVED THE RESULTS OF
HER ANNUAL MAMMOGRAM,
COMPLETED LAST WEEK. AS
PER THE PATIENT, SHE WAS
DIAGNOSED WITH A
GLANDULAR LOBULAR
CARCINOMA IN HER LEFT
BREAST. PATIENT STATES SHE
NEVER FELT A LUMP, NOR
DOES SHE FEEL ONE NOW. THE
CARCINOMA WAS
DISCOVERED VIA THE
MAMMOGRAM. AT THIS TIME,
PATIENT STATES THAT SHE
DOES NOT WANT TO PUT
HERSELF THROUGH
RADIATION OR
CHEMOTHERAPY AND PLANS
TO HAVE A TOTAL
MASTECTOMY DONE. PATIENT
HAS A FOLLOW-UP SURGERY
CONSULT SCHEDULED AND
WILL FOLLOW UP WITH STUDY
STAFF IN REGARDS TO HER
TREATMENT PLAN.

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)	
--	--

US3292365

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 May 2021 20:04:29

Generated On: 09 Jun 2021 16:27:54

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 May 2021 20:04:29

Generated On: 09 Jun 2021 16:27:54

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

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 18:44:18

Generated On: 09 Jun 2021 16:27:54

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 May 2021 20:04:29

Generated On: 09 Jun 2021 16:27:54

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR CARDIAC
PREVENTATIVE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 May 2021 20:04:29

Generated On: 09 Jun 2021 16:27:54

	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 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	11 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 May 2021 20:04:29

Generated On: 09 Jun 2021 16:27:54

Name of Medication VITAMIN C

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH
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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 May 2021 20:04:29

Generated On: 09 Jun 2021 16:27:54

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 May 2021 20:04:29

Generated On: 09 Jun 2021 16:27:54

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication GENERAL ACHES

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 May 2021 20:04:29

Generated On: 09 Jun 2021 16:27:54

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 May 2021 20:04:29

Generated On: 09 Jun 2021 16:27:54

Name of Medication ZINC

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH
SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 May 2021 20:04:29

Generated On: 09 Jun 2021 16:27:54

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 May 2021 20:04:29

Generated On: 09 Jun 2021 16:27:54

Name of Medication DULOXETINE HCL DR

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 60

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 May 2021 20:04:29

Generated On: 09 Jun 2021 16:27:54

	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 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 May 2021 20:04:29

Generated On: 09 Jun 2021 16:27:54

Name of Medication MONTELUKAST SODIUM

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 May 2021 20:04:29

Generated On: 09 Jun 2021 16:27:54

	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 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 May 2021 20:04:29

Generated On: 09 Jun 2021 16:27:54

Name of Medication PROAIR RESPICLICK

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 90

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 May 2021 20:04:29

Generated On: 09 Jun 2021 16:27:54

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" 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 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 May 2021 20:04:29

Generated On: 09 Jun 2021 16:27:54

Name of Medication ARNUITY ELLIPTA

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 May 2021 20:04:29

Generated On: 09 Jun 2021 16:27:54

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 May 2021 20:04:29

Generated On: 09 Jun 2021 16:27:54

Name of Medication SUMATRIPTAN SUCCINATE

Prophylaxis Yes ☐
No ☒

Indication MIGRAINE

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 May 2021 20:04:29

Generated On: 09 Jun 2021 16:27:54

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

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 03 May 2021 20:04:29

Generated On: 09 Jun 2021 16:27:54

Name of Medication PROGESTERONE

Prophylaxis Yes ☐
No ☒

Indication HOT FLASHES

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 03 May 2021 20:04:29

Generated On: 09 Jun 2021 16:27:54

	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	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	12 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 03 May 2021 20:04:29

Generated On: 09 Jun 2021 16:27:54

Name of Medication ESTRADIOL

Prophylaxis Yes ☐
No ☒

Indication MENOPAUSE

Dose per administration 0.05

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

BIWEEKLY

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 03 May 2021 20:04:29

Generated On: 09 Jun 2021 16:27:54

	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	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	12 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 03 May 2021 20:04:29

Generated On: 09 Jun 2021 16:27:54

Name of Medication TRETINOIN CREAM 0.05%

Prophylaxis Yes ☐
No ☒

Indication ACNE

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 03 May 2021 20:04:29

Generated On: 09 Jun 2021 16:27:54

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

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 03 May 2021 20:04:29

Generated On: 09 Jun 2021 16:27:54

Name of Medication TOBRAMYCIN 0.3%

Prophylaxis Yes ☐
No ☒

Indication CONJUNCTIVITIS

Dose per administration 2

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

If dose unit is Other, specify DROPS

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

If frequency is Other, specify EVERY FOUR HOURS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 03 May 2021 20:04:29

Generated On: 09 Jun 2021 16:27:54

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify		OPHTHALMOLOGIC
Start date (dd MMM yyyy)	23 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		9 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 03 May 2021 20:04:29

Generated On: 09 Jun 2021 16:27:54

Name of Medication ANASTROZOLE

Prophylaxis Yes ☐
No ☒

Indication INVASIVE LOBULAR
CARCINOMA

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 03 May 2021 20:04:29

Generated On: 09 Jun 2021 16:27:54

	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)		25 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3292365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Feb 2021 18:44:18

Generated On: 09 Jun 2021 16:27:54

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 03 May 2021 20:04:30

Generated On: 09 Jun 2021 16:27:54

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
8 OCT 2020	MAMMOGRAM	Diagnostic	
29 OCT 2020	MAMMOGRAM	Diagnostic	
3 NOV 2020	LEFT BREAST BIOPSY	Diagnostic	
14 JAN 2021	MASTECTOMY	Adverse Event	
5 APR 2021	RECONSTRUCTION BREAST REVISION	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:27:54

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:27:54

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

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Data signed: (b) (4) 23 Feb 2021 18:44:18

Generated On: 09 Jun 2021 16:27:54

SAEID	USA-US072-2020-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Feb 2021 18:44:18

Generated On: 09 Jun 2021 16:27:54

SAEID	USA-US072-2020-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	10/NOV/2020 18:41
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Feb 2021 18:44:18

Generated On: 09 Jun 2021 16:27:54

SAEID	USA-US072-2020-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	24/NOV/2020 12:32
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form (3)

Data signed: (b) (4) 23 Feb 2021 18:44:18

Generated On: 09 Jun 2021 16:27:54

SAEID	USA-US072-2020-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	25/NOV/2020 15:32
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form (4)

Data signed: (b) (4) 23 Feb 2021 18:44:18

Generated On: 09 Jun 2021 16:27:54

SAEID	USA-US072-2020-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	27/JAN/2021 14:46
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form (5)

Data signed: (b) (4) 23 Feb 2021 18:44:18

Generated On: 09 Jun 2021 16:27:54

SAEID	USA-US072-2020-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	19/FEB/2021 11:11
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3292365 (Prod: Clinical Trials of Texas, Inc)

US3292365

Form: Participant Creation

Generated On: 09 Jun 2021 16:27:54

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:25:39
User entered 'US3292365'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 15:30:46

US3292365

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:27:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:47:42

US3292365

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '29 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 15:30:47

US3292365

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:27:54

[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 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	01 Sep 2020 03:47:42

US3292365

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:27:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'SCRN'	System	01 Sep 2020 03:47:42

US3292365

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:54

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered (b) (6) 1962'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 15:30:48

US3292365

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:54

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '58'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:48:01

US3292365

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:54

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'YEARS'	System	01 Sep 2020 03:48:01

US3292365

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:54

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '58'	System	29 Aug 2020 18:20:56

US3292365

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:54

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:48:01

US3292365

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:54

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	01 Sep 2020 03:48:01

US3292365

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:54

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'l'	(b) (4), (b) (6)	01 Sep 2020 03:48:01

US3292365

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:54

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 03:48:01

US3292365

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:54

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:48:01

US3292365

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:54

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 03:48:01

US3292365

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:54

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 03:48:01

US3292365

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:54

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 03:48:01

US3292365

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:54

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:48:01

US3292365

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:54

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:48:01

US3292365

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:54

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:48:01

US3292365

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:27:54

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '29 Aug 2020'	(b) (4), (b) (6)	29 Aug 2020 18:20:56

US3292365

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Aug 2020'	System	29 Aug 2020 18:20:56

US3292365

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '2020'	System	29 Aug 2020 18:20:56

US3292365

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:27:54

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	29 Aug 2020 18:20:56

US3292365

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 18:20:56

US3292365

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:27:54

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:20:56

US3292365

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:27:54

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:20:56

US3292365

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:27:54

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 18:20:56

US3292365

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:27:54

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 15:30:47

US3292365

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:27:54

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'l'	System	29 Aug 2020 18:21:02

US3292365

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 18:21:02

US3292365

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:27:54

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 03:48:11

US3292365

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:27:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Mycotic allergy, LLT: Allergy to molds - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 03:50:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 03:50:44
Data point term sent to Coder	System	01 Sep 2020 03:50:07
User entered 'Mold allergy'	(b) (4), (b) (6)	01 Sep 2020 03:49:11

US3292365

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'un UNK 1984'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:49:11

US3292365

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 03:49:11

US3292365

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:27:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 03:49:11

US3292365

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:49:11

US3292365

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:27:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 03:49:11

US3292365

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Jan 1984'	System	01 Sep 2020 03:49:11

US3292365

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:27:54

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '1984'	System	01 Sep 2020 03:49:11

US3292365

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered empty.	System	01 Sep 2020 03:49:11

US3292365

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered empty.	System	01 Sep 2020 03:49:11

US3292365

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:27:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Allergy to plants, LLT: Allergy to plants - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 18:10:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 18:10:01
Data point term sent to Coder	System	01 Sep 2020 03:50:07
User entered 'oak allergy'	(b) (4), (b) (6)	01 Sep 2020 03:49:26

US3292365

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'un UNK 1984'	(b) (4), (b) (6)	01 Sep 2020 03:49:26

US3292365

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 03:49:26

US3292365

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:27:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 03:49:26

US3292365

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:49:26

US3292365

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:27:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 03:49:26

US3292365

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Jan 1984'	System	01 Sep 2020 03:49:26

US3292365

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:27:54

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '1984'	System	01 Sep 2020 03:49:26

US3292365

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered empty.	System	01 Sep 2020 03:49:26

US3292365

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered empty.	System	01 Sep 2020 03:49:26

US3292365

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:27:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Allergy to arthropod sting, LLT: Allergic reaction to bee sting - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:25:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:25:13
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Allergy to arthropod sting, LLT: Bee sting hypersensitivity - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 03:51:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 03:51:45
Data point term sent to Coder	System	01 Sep 2020 03:51:08
User entered 'bee sting allergy'	(b) (4), (b) (6)	01 Sep 2020 03:50:32

US3292365

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'un UNK 1981'	(b) (4), (b) (6)	01 Sep 2020 03:50:32

US3292365

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 03:50:32

US3292365

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:27:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 03:50:32

US3292365

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:50:32

US3292365

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:27:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 03:50:32

US3292365

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Jan 1981'	System	01 Sep 2020 03:50:32

US3292365

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:27:54

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '1981'	System	01 Sep 2020 03:50:32

US3292365

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered empty.	System	01 Sep 2020 03:50:32

US3292365

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered empty.	System	01 Sep 2020 03:50:32

US3292365

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:27:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Vaginal therapeutic procedures, PT: Hymenectomy, LLT: Hymenectomy - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 04:08:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 04:08:43
Data point term sent to Coder	System	01 Sep 2020 04:08:27
User entered 'hymenectomy'	(b) (4), (b) (6)	01 Sep 2020 04:08:24

US3292365

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'un UNK 1985'	(b) (4), (b) (6)	01 Sep 2020 04:08:24

US3292365

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:08:24

US3292365

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:27:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:08:24

US3292365

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'un UNK 1985'	(b) (4), (b) (6)	01 Sep 2020 04:08:24

US3292365

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:27:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:08:24

US3292365

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Jan 1985'	System	01 Sep 2020 04:08:24

US3292365

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:27:54

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '1985'	System	01 Sep 2020 04:08:24

US3292365

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Jan 1985'	System	01 Sep 2020 04:08:24

US3292365

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '1985'	System	01 Sep 2020 04:08:24

US3292365

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:27:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Reproductive tract and breast disorders congenital, HLT: Female reproductive tract disorders congenital, PT: Septate hymen, LLT: Septate hymen - version MedDRA\23.0.	Coder Import (b) (4)	01 Sep 2020 08:41:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	01 Sep 2020 08:41:49
Data point term sent to Coder	System	01 Sep 2020 04:23:40
Coding entries removed.	(b) (4), (b) (6)	01 Sep 2020 04:23:25
User entered 'thick/SEPTATE HYMEN' reason for change: Data Entry Error		01 Sep 2020 04:23:25
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Reproductive tract and breast disorders congenital, HLT: Female reproductive tract disorders congenital, PT: Septate hymen, LLT: Septate hymen - version MedDRA\23.0.	Coder Import (b) (4)	01 Sep 2020 04:11:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	01 Sep 2020 04:11:40
Data point term sent to Coder	System	01 Sep 2020 04:10:28
User entered 'septate hymen'	(b) (4), (b) (6)	01 Sep 2020 04:09:37

US3292365

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'un UNK 1985'	(b) (4), (b) (6)	01 Sep 2020 04:09:37

US3292365

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:09:37

US3292365

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:27:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:09:37

US3292365

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'un UNK 1985'	(b) (4), (b) (6)	01 Sep 2020 04:09:37

US3292365

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:27:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:09:37

US3292365

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Jan 1985'	System	01 Sep 2020 04:09:37

US3292365

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:27:54

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '1985'	System	01 Sep 2020 04:09:37

US3292365

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Jan 1985'	System	01 Sep 2020 04:09:37

US3292365

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '1985'	System	01 Sep 2020 04:09:37

US3292365

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:27:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: C-section - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	01 Sep 2020 04:13:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 04:13:42
Data point term sent to Coder	System	01 Sep 2020 04:12:28
User entered 'C-section'	(b) (4), (b) (6)	01 Sep 2020 04:11:29

US3292365

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'un UNK 1989'	(b) (4), (b) (6)	01 Sep 2020 04:11:29

US3292365

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:11:29

US3292365

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:27:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:11:29

US3292365

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'un UNK 1989'	(b) (4), (b) (6)	01 Sep 2020 04:11:29

US3292365

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:27:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:11:29

US3292365

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Jan 1989'	System	01 Sep 2020 04:11:29

US3292365

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:27:54

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '1989'	System	01 Sep 2020 04:11:29

US3292365

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Jan 1989'	System	01 Sep 2020 04:11:29

US3292365

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '1989'	System	01 Sep 2020 04:11:29

US3292365

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:27:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User closed query 'Per DM CLR: Please specify the type of LAPROSCOPY (laparoscopic cholecystectomy, laparoscopic splenectomy, rtc.). Please ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 23:21:37
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Endometriosis, LLT: Endometriosis - version MedDRA\23.0.	Coder Import (b) (4)	23 Sep 2020 14:39:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Sep 2020 14:39:39
Data point term sent to Coder	System	23 Sep 2020 14:38:53
Query 'Per DM CLR: Please specify the type of LAPROSCOPY (laparoscopic cholecystectomy, laparoscopic splenectomy, rtc.). Please ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 14:38:03
Coding entries removed.		23 Sep 2020 14:37:55
User entered 'Laparoscopy for endometriosis' reason for change: Data Entry Error		23 Sep 2020 14:37:55
User opened query 'Per DM CLR: Please specify the type of LAPROSCOPY (laparoscopic cholecystectomy, laparoscopic splenectomy, rtc.). Please ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).		09 Sep 2020 21:24:52

US3292365

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:27:54

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLGT: Gastrointestinal investigations, HLT: Gastrointestinal and abdominal imaging procedures, PT: Laparoscopy, LLT: Laparoscopy - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 04:13:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 04:13:41
Data point term sent to Coder	System	01 Sep 2020 04:12:28
User entered 'laparoscopy'	(b) (4), (b) (6)	01 Sep 2020 04:12:15

US3292365

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'un UNK 1997'	(b) (4), (b) (6)	01 Sep 2020 04:12:15

US3292365

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:27:54

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:12:15

US3292365

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:27:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:12:15

US3292365

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'un UNK 1997'	(b) (4), (b) (6)	01 Sep 2020 04:12:15

US3292365

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:27:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:12:15

US3292365

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Jan 1997'	System	01 Sep 2020 04:12:15

US3292365

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:27:54

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '1997'	System	01 Sep 2020 04:12:15

US3292365

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Jan 1997'	System	01 Sep 2020 04:12:15

US3292365

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '1997'	System	01 Sep 2020 04:12:15

US3292365

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:27:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Endometriosis, LLT: Endometriosis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	01 Sep 2020 04:14:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 04:14:43
Data point term sent to Coder	System	01 Sep 2020 04:13:29
User entered 'endometriosis'	(b) (4), (b) (6)	01 Sep 2020 04:13:10

US3292365

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'un UNK 1997'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:13:10

US3292365

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:13:10

US3292365

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:27:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:13:10

US3292365

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'un UNK 1997'	(b) (4), (b) (6)	01 Sep 2020 04:13:10

US3292365

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:27:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:13:10

US3292365

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Jan 1997'	System	01 Sep 2020 04:13:10

US3292365

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:27:54

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '1997'	System	01 Sep 2020 04:13:10

US3292365

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Jan 1997'	System	01 Sep 2020 04:13:10

US3292365

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '1997'	System	01 Sep 2020 04:13:10

US3292365

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:27:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Corneal and scleral therapeutic procedures, PT: Keratomileusis, LLT: LASIK eye surgery - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 04:15:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 04:15:44
Data point term sent to Coder	System	01 Sep 2020 04:14:29
User entered 'right eye lasik'	(b) (4), (b) (6)	01 Sep 2020 04:13:42

US3292365

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '06 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 04:13:42

US3292365

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:13:42

US3292365

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:27:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:13:42

US3292365

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '06 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 04:13:42

US3292365

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:27:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:13:42

US3292365

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Aug 2020'	System	01 Sep 2020 04:13:42

US3292365

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:27:54

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '2020'	System	01 Sep 2020 04:13:42

US3292365

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Aug 2020'	System	01 Sep 2020 04:13:42

US3292365

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '2020'	System	01 Sep 2020 04:13:42

US3292365

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:27:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User coded data point as SOC: Investigations, HLT: Gastrointestinal investigations, HLT: Gastrointestinal and abdominal imaging procedures, PT: Colonoscopy, LLT: Colonoscopy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	01 Sep 2020 04:15:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 04:15:44
Data point term sent to Coder	System	01 Sep 2020 04:14:30
User entered 'colonoscopy'	(b) (4), (b) (6)	01 Sep 2020 04:14:22

US3292365

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'un UNK 2015'	(b) (4), (b) (6)	01 Sep 2020 04:14:22

US3292365

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:14:22

US3292365

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:27:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:14:22

US3292365

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'un UNK 2015'	(b) (4), (b) (6)	01 Sep 2020 04:14:22

US3292365

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:27:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:14:22

US3292365

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Jan 2015'	System	01 Sep 2020 04:14:22

US3292365

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:27:54

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '2015'	System	01 Sep 2020 04:14:22

US3292365

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Jan 2015'	System	01 Sep 2020 04:14:22

US3292365

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '2015'	System	01 Sep 2020 04:14:22

US3292365

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:27:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Polypectomy, LLT: Polyp removal - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	01 Sep 2020 04:16:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 04:16:36
Data point term sent to Coder	System	01 Sep 2020 04:15:30
User entered 'polyp removal'	(b) (4), (b) (6)	01 Sep 2020 04:14:47

US3292365

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'un UNK 2015'	(b) (4), (b) (6)	01 Sep 2020 04:14:47

US3292365

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:14:47

US3292365

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:27:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:14:47

US3292365

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'un UNK 2015'	(b) (4), (b) (6)	01 Sep 2020 04:14:47

US3292365

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:27:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:14:47

US3292365

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Jan 2015'	System	01 Sep 2020 04:14:47

US3292365

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:27:54

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '2015'	System	01 Sep 2020 04:14:47

US3292365

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Jan 2015'	System	01 Sep 2020 04:14:47

US3292365

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '2015'	System	01 Sep 2020 04:14:47

US3292365

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:27:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Cancer surgery, LLT: Squamous cell carcinoma excision - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	01 Sep 2020 07:34:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	01 Sep 2020 07:34:51
Data point term sent to Coder	System	01 Sep 2020 04:16:32
User entered 'left hand squamous cell removal'	(b) (4), (b) (6)	01 Sep 2020 04:15:59

US3292365

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'un UNK 2009'	(b) (4), (b) (6)	01 Sep 2020 04:15:59

US3292365

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:15:59

US3292365

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:27:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:15:59

US3292365

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'un UNK 2009'	(b) (4), (b) (6)	01 Sep 2020 04:15:59

US3292365

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:27:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:15:59

US3292365

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Jan 2009'	System	01 Sep 2020 04:15:59

US3292365

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:27:54

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '2009'	System	01 Sep 2020 04:15:59

US3292365

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Jan 2009'	System	01 Sep 2020 04:15:59

US3292365

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '2009'	System	01 Sep 2020 04:15:59

US3292365

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:27:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Miscellaneous and site unspecified neoplasms malignant and unspecified, HLT: Neoplasms malignant site unspecified NEC, PT: Squamous cell carcinoma, LLT: Squamous cell carcinoma - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	01 Sep 2020 07:34:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 07:34:51
Data point term sent to Coder	System	01 Sep 2020 04:16:31
User entered 'left hand squamous cell carcinoma'	(b) (4), (b) (6)	01 Sep 2020 04:16:17

US3292365

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'un UNK 2009'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:16:17

US3292365

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:16:17

US3292365

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:27:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:16:17

US3292365

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'un UNK 2009'	(b) (4), (b) (6)	01 Sep 2020 04:16:17

US3292365

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:27:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:16:17

US3292365

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Jan 2009'	System	01 Sep 2020 04:16:17

US3292365

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:27:54

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '2009'	System	01 Sep 2020 04:16:17

US3292365

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Jan 2009'	System	01 Sep 2020 04:16:17

US3292365

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '2009'	System	01 Sep 2020 04:16:17

US3292365

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:27:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin lesion excisions, PT: Skin neoplasm excision, LLT: Basal cell carcinoma excision - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	01 Sep 2020 07:41:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	01 Sep 2020 07:41:37
Data point term sent to Coder	System	01 Sep 2020 04:17:32
User entered 'left hand and foot basal cell removal'	(b) (4), (b) (6)	01 Sep 2020 04:17:13

US3292365

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'un UNK 2017'	(b) (4), (b) (6)	01 Sep 2020 04:17:13

US3292365

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:17:13

US3292365

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:27:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:17:13

US3292365

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'un UNK 2017'	(b) (4), (b) (6)	01 Sep 2020 04:17:13

US3292365

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:27:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:17:13

US3292365

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Jan 2017'	System	01 Sep 2020 04:17:13

US3292365

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:27:54

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '2017'	System	01 Sep 2020 04:17:13

US3292365

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Jan 2017'	System	01 Sep 2020 04:17:13

US3292365

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '2017'	System	01 Sep 2020 04:17:13

US3292365

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:27:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGt: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	01 Sep 2020 07:36:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 07:36:44
Data point term sent to Coder	System	01 Sep 2020 04:18:33
User entered 'left hand and foot basal cell carcinoma'	(b) (4), (b) (6)	01 Sep 2020 04:17:53

US3292365

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'un UNK 2017'	(b) (4), (b) (6)	01 Sep 2020 04:17:53

US3292365

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:17:53

US3292365

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:27:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:17:53

US3292365

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'un UNK 2017'	(b) (4), (b) (6)	01 Sep 2020 04:17:53

US3292365

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:27:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:17:53

US3292365

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Jan 2017'	System	01 Sep 2020 04:17:53

US3292365

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:27:54

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '2017'	System	01 Sep 2020 04:17:53

US3292365

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Jan 2017'	System	01 Sep 2020 04:17:53

US3292365

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '2017'	System	01 Sep 2020 04:17:53

US3292365

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:27:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User closed query 'Per DM CLR: Please specify the location (bilateral, left, right) of DECREASED VISUAL ACUITY. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 16:19:47
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Visual impairment and blindness (excl colour blindness), PT: Visual acuity reduced, LLT: Visual acuity decreased - version MedDRA\23.0.	Coder Import (b) (4)	23 Sep 2020 14:43:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	23 Sep 2020 14:43:38
Query 'Per DM CLR: Please specify the location (bilateral, left, right) of DECREASED VISUAL ACUITY. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 14:42:59
Data point term sent to Coder	System	23 Sep 2020 14:42:59
Coding entries removed.	(b) (4), (b) (6)	23 Sep 2020 14:42:50
User entered 'bilateral DECREASED VISUAL ACUITY' reason for change: Data Entry Error		09 Sep 2020 21:26:12
User opened query 'Per DM CLR: Please specify the location (bilateral, left, right) of DECREASED VISUAL ACUITY. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).		
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Visual impairment and blindness (excl colour blindness), PT: Visual acuity reduced, LLT: Visual acuity decreased - version MedDRA\23.0.	Coder Import (b) (4)	01 Sep 2020 04:19:36

US3292365

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:27:54

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	01 Sep 2020 04:19:36
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	01 Sep 2020 04:18:34
User entered 'decreased visual acuity'	(b) (4), (b) (6)	01 Sep 2020 04:18:13

US3292365

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'un UNK 2005'	(b) (4), (b) (6)	01 Sep 2020 04:18:13

US3292365

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:18:13

US3292365

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:27:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 04:18:13

US3292365

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:18:13

US3292365

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:27:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:18:13

US3292365

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Jan 2005'	System	01 Sep 2020 04:18:13

US3292365

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:27:54

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '2005'	System	01 Sep 2020 04:18:13

US3292365

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered empty.	System	01 Sep 2020 04:18:13

US3292365

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered empty.	System	01 Sep 2020 04:18:13

US3292365

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:27:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Chronic cough - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	01 Sep 2020 04:19:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 04:19:36
Data point term sent to Coder	System	01 Sep 2020 04:18:33
User entered 'chronic cough'	(b) (4), (b) (6)	01 Sep 2020 04:18:32

US3292365

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'un UNK 1977'	(b) (4), (b) (6)	01 Sep 2020 04:18:32

US3292365

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:18:32

US3292365

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:27:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 04:18:32

US3292365

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:18:32

US3292365

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:27:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:18:32

US3292365

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Jan 1977'	System	01 Sep 2020 04:18:32

US3292365

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:27:54

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '1977'	System	01 Sep 2020 04:18:32

US3292365

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered empty.	System	01 Sep 2020 04:18:32

US3292365

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered empty.	System	01 Sep 2020 04:18:32

US3292365

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:27:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	01 Sep 2020 04:20:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 04:20:37
Data point term sent to Coder	System	01 Sep 2020 04:19:34
User entered 'asthma'	(b) (4), (b) (6)	01 Sep 2020 04:18:46

US3292365

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'UN UNK 1998' reason for change:	(b) (4)	
Data Entry Error	Kevin Martinez (b) (4)	05 Nov 2020 19:17:00
User entered 'un UNK 2009'	(b) (4), (b) (6)	01 Sep 2020 04:18:46

US3292365

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:18:46

US3292365

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:27:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 04:18:46

US3292365

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:18:46

US3292365

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:27:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:18:46

US3292365

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Jan 1998'	System	05 Nov 2020 19:17:00
User entered 'Jan 2009'	System	01 Sep 2020 04:18:46

US3292365

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:27:54

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '1998'	System	05 Nov 2020 19:17:00
User entered '2009'	System	01 Sep 2020 04:18:46

US3292365

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered empty.	System	01 Sep 2020 04:18:46

US3292365

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered empty.	System	01 Sep 2020 04:18:46

US3292365

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:27:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User closed query 'Per DM CLR: Please update the condition to confirm if the COLON POLYP was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 16:20:03
User coded data point as SOC: Gastrointestinal disorders, HLGT: Benign neoplasms gastrointestinal, HLT: Benign neoplasms gastrointestinal (excl oral cavity), PT: Large intestine polyp, LLT: Benign colonic polyp - version MedDRA\23.0.	Coder Import (b) (4)	23 Sep 2020 20:27:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Sep 2020 20:27:14
Query 'Per DM CLR: Please update the condition to confirm if the COLON POLYP was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 14:42:08
Data point term sent to Coder	System	23 Sep 2020 14:41:58
Coding entries removed.	(b) (4), (b) (6)	23 Sep 2020 14:41:56
User entered 'COLON POLYP benign' reason for change: Data Entry Error		23 Sep 2020 14:41:56
User opened query 'Per DM CLR: Please update the condition to confirm if the COLON POLYP was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).		09 Sep 2020 21:26:43
User coded data point as SOC: Gastrointestinal disorders, HLGT: Benign neoplasms gastrointestinal, HLT: Benign neoplasms gastrointestinal (excl oral cavity), PT: Large intestine polyp, LLT: Colonic polyp - version MedDRA\23.0.	Coder Import (b) (4)	01 Sep 2020 04:21:37

US3292365

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:27:54

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	01 Sep 2020 04:21:37
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	01 Sep 2020 04:20:38
User entered 'colon polyp'	(b) (4), (b) (6)	01 Sep 2020 04:20:07

US3292365

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'un UNK 2012'	(b) (4), (b) (6)	01 Sep 2020 04:20:07

US3292365

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:20:07

US3292365

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:27:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:20:07

US3292365

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'un UNK 2015'	(b) (4), (b) (6)	01 Sep 2020 04:20:07

US3292365

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:27:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:20:07

US3292365

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Jan 2012'	System	01 Sep 2020 04:20:07

US3292365

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:27:54

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '2012'	System	01 Sep 2020 04:20:07

US3292365

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Jan 2015'	System	01 Sep 2020 04:20:07

US3292365

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '2015'	System	01 Sep 2020 04:20:07

US3292365

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:27:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 04:22:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 04:22:38
Data point term sent to Coder	System	01 Sep 2020 04:21:38
User entered 'anxiety'	(b) (4), (b) (6)	01 Sep 2020 04:20:45

US3292365

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'un UNK 2010'	(b) (4), (b) (6)	01 Sep 2020 04:20:45

US3292365

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:20:45

US3292365

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:27:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 04:20:45

US3292365

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:20:45

US3292365

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:27:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:20:45

US3292365

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Jan 2010'	System	01 Sep 2020 04:20:45

US3292365

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:27:54

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '2010'	System	01 Sep 2020 04:20:45

US3292365

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered empty.	System	01 Sep 2020 04:20:45

US3292365

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered empty.	System	01 Sep 2020 04:20:45

US3292365

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:27:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	01 Sep 2020 04:22:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 04:22:39
Data point term sent to Coder	System	01 Sep 2020 04:21:39
User entered 'migraines'	(b) (4), (b) (6)	01 Sep 2020 04:21:04

US3292365

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'un UNK 1993'	(b) (4), (b) (6)	01 Sep 2020 04:21:04

US3292365

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:21:04

US3292365

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:27:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 04:21:04

US3292365

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:21:04

US3292365

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:27:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:21:04

US3292365

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Jan 1993'	System	01 Sep 2020 04:21:04

US3292365

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:27:54

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '1993'	System	01 Sep 2020 04:21:04

US3292365

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered empty.	System	01 Sep 2020 04:21:04

US3292365

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered empty.	System	01 Sep 2020 04:21:04

US3292365

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:27:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User closed query 'Per DM CLR: Please specify the location and/or type of ACNE. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 23:22:18
Query 'Per DM CLR: Please specify the location and/or type of ACNE. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'unknown, attempted patient contact no answer' (Site from DM).		23 Sep 2020 14:44:05
User opened query 'Per DM CLR: Please specify the location and/or type of ACNE. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).		09 Sep 2020 21:27:12
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Acnes, PT: Acne, LLT: Acne - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 04:22:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 04:22:39
Data point term sent to Coder	System	01 Sep 2020 04:21:39
User entered 'acne'	(b) (4), (b) (6)	01 Sep 2020 04:21:17

US3292365

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'un UNK 1970'	(b) (4), (b) (6)	01 Sep 2020 04:21:17

US3292365

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:21:17

US3292365

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:27:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 04:21:17

US3292365

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:21:17

US3292365

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:27:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:21:17

US3292365

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Jan 1970'	System	01 Sep 2020 04:21:17

US3292365

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:27:54

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '1970'	System	01 Sep 2020 04:21:17

US3292365

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered empty.	System	01 Sep 2020 04:21:17

US3292365

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered empty.	System	01 Sep 2020 04:21:17

US3292365

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:27:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User coded data point as SOC: Vascular disorders, HLT: Vascular disorders NEC, HLT: Peripheral vascular disorders NEC, PT: Hot flush, LLT: Hot flashes - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	01 Sep 2020 04:23:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 04:23:41
Data point term sent to Coder	System	01 Sep 2020 04:22:40
User entered 'hot flashes'	(b) (4), (b) (6)	01 Sep 2020 04:22:01

US3292365

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'un UNK 2008'	(b) (4), (b) (6)	01 Sep 2020 04:22:01

US3292365

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:22:01

US3292365

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:27:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 04:22:01

US3292365

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:22:01

US3292365

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:27:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:22:01

US3292365

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Jan 2008'	System	01 Sep 2020 04:22:01

US3292365

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:27:54

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '2008'	System	01 Sep 2020 04:22:01

US3292365

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered empty.	System	01 Sep 2020 04:22:01

US3292365

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered empty.	System	01 Sep 2020 04:22:01

US3292365

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 16:27:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User closed query 'Per DM CLR: Please update the condition to confirm if the LEFT OVARIAN CYST was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 16:20:29
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Ovarian cyst, LLT: Benign ovarian cyst - version MedDRA\23.0.	Coder Import (b) (4)	23 Sep 2020 19:03:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Sep 2020 19:03:49
Data point term sent to Coder	System	23 Sep 2020 14:45:11
Query 'Per DM CLR: Please update the condition to confirm if the LEFT OVARIAN CYST was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 14:44:36
Coding entries removed.		23 Sep 2020 14:44:27
User entered 'benign LEFT OVARIAN CYST' reason for change: Data Entry Error		23 Sep 2020 14:44:27
User opened query 'Per DM CLR: Please update the condition to confirm if the LEFT OVARIAN CYST was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).		09 Sep 2020 21:27:39
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Ovarian cyst, LLT: Ovarian cyst - version MedDRA\23.0.	Coder Import (b) (4)	01 Sep 2020 07:36:44

US3292365

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 16:27:54

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	01 Sep 2020 07:36:44
Data point term sent to Coder	System	01 Sep 2020 04:23:41
User entered 'left ovarian cyst'	(b) (4), (b) (6)	01 Sep 2020 04:22:41

US3292365

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'un UNK 2015'	(b) (4), (b) (6)	01 Sep 2020 04:22:41

US3292365

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:22:41

US3292365

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 16:27:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 04:22:41

US3292365

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:22:41

US3292365

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 16:27:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:22:41

US3292365

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Jan 2015'	System	01 Sep 2020 04:22:41

US3292365

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 16:27:54

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '2015'	System	01 Sep 2020 04:22:41

US3292365

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered empty.	System	01 Sep 2020 04:22:41

US3292365

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered empty.	System	01 Sep 2020 04:22:41

US3292365

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:27:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 14:49:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 14:49:35
Data point term sent to Coder	System	23 Sep 2020 14:48:55
User entered 'Post-Menopausal'	(b) (4), (b) (6)	23 Sep 2020 14:48:29

US3292365

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'UN UNK 2014'	(b) (4), (b) (6)	23 Sep 2020 14:48:29

US3292365

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 14:48:29

US3292365

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:27:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 14:48:29

US3292365

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:48:29

US3292365

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:27:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 14:48:29

US3292365

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Jan 2014'	System	23 Sep 2020 14:48:29

US3292365

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:27:54

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '2014'	System	23 Sep 2020 14:48:29

US3292365

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered empty.	System	23 Sep 2020 14:48:29

US3292365

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered empty.	System	23 Sep 2020 14:48:29

US3292365

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:27:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: Generalized aching - version MedDRA\\23.0.	Coder Import (b) (4)	26 Mar 2021 14:51:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Mar 2021 14:51:47
Data point term sent to Coder	System	26 Mar 2021 14:51:18
User entered 'General Aches'	Nathan Cortez (b) (4)	26 Mar 2021 14:51:03

US3292365

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'UN Aug 2020'	(b) (4) Nathan Cortez (b) (4)	26 Mar 2021 14:51:03

US3292365

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered '0'	(b) (4) Nathan Cortez (b) (4)	26 Mar 2021 14:51:03

US3292365

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:27:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	26 Mar 2021 14:51:03

US3292365

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4) Nathan Cortez (b) (4)	26 Mar 2021 14:51:03

US3292365

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:27:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered '0'	(b) (4) Nathan Cortez (b) (4)	26 Mar 2021 14:51:03

US3292365

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'Aug 2020'	System	26 Mar 2021 14:51:03

US3292365

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '2020'	System	26 Mar 2021 14:51:03

US3292365

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered empty.	System	26 Mar 2021 14:51:03

US3292365

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered empty.	System	26 Mar 2021 14:51:03

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 04:26:16

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '29 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 04:26:16

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '10:11'	(b) (4), (b) (6)	01 Sep 2020 04:26:16

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '29 Aug 2020 10:11'	System	01 Sep 2020 04:26:16

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '179.4' cm	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:26:16
DataPoint set to visible.	System	29 Aug 2020 18:21:02

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '92.0' kg	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:26:16
DataPoint set to visible.	System	29 Aug 2020 18:21:02

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '28.58531'	System	01 Sep 2020 04:26:16
DataPoint set to visible.	System	29 Aug 2020 18:21:02

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'kg/m2'	System	01 Sep 2020 04:26:16
DataPoint set to visible.	System	29 Aug 2020 18:21:02

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 04:26:16

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User closed query 'Per CDM: Please remove data from this field, as this should be 'blank' if 'Temperature' is Not Done. Thanks ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 09:16:26
Query 'Per CDM: Please remove data from this field, as this should be 'blank' if 'Temperature' is Not Done. Thanks ' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	21 Dec 2020 19:24:04
User entered empty; reason for change Data Entry Error	Dawn Killian (b) (4)	21 Dec 2020 19:23:46
User opened query 'Per CDM: Please remove data from this field, as this should be 'blank' if 'Temperature' is Not Done. Thanks ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 17:37:27
User entered 'Other (Other)'	(b) (4), (b) (6)	01 Sep 2020 04:26:16

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User closed query 'Per CDM: Please remove the data as this field should be "blank". ' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 13:32:48
Query 'Per CDM: Please remove the data as this field should be "blank". ' answered with 'updated' (Site from DM).	Kevin Martinez (b) (4)	30 Dec 2020 18:40:23
User entered empty; reason for change Data Entry Error	Kevin Martinez (b) (4)	30 Dec 2020 18:40:09
User opened query 'Per CDM: Please remove the data as this field should be "blank". ' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 14:26:31
User entered missing code ND - Not Done.		01 Sep 2020 04:26:16

Pulse (xxx)

PRODUCTION RELEASE (v12.003
EAB) (1725)

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	31 Dec 2020 13:32:51
Query 'Data is required. Please provide.' answered with 'not done' (Site from System).	Kevin Martinez (b) (4)	30 Dec 2020 18:40:25
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	30 Dec 2020 18:40:09
User entered empty; reason for change Data Entry Error	Kevin Martinez (b) (4)	30 Dec 2020 18:40:09
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 04:26:16

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'bpm'	System	31 Dec 2020 17:53:35
User entered empty.	System	30 Dec 2020 18:40:09
User entered 'bpm'	System	01 Sep 2020 04:26:16

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	31 Dec 2020 17:53:35
User closed query 'Data is required. Please provide.' (Site from System).	Kevin Martinez (b) (4)	31 Dec 2020 13:32:53
Query 'Data is required. Please provide.' answered with 'not done' (Site from System).	(b) (4), (b) (6)	31 Dec 2020 13:32:53
User opened query 'Data is required. Please provide.' (Site from System).	Kevin Martinez (b) (4)	30 Dec 2020 18:40:27
User entered empty; reason for change Data Entry Error	(b) (4)	30 Dec 2020 18:40:09
User entered missing code ND - Not Done.	System	30 Dec 2020 18:40:09
	Kevin Martinez (b) (4)	30 Dec 2020 18:40:09
	(b) (4)	30 Dec 2020 18:40:09
	(b) (4), (b) (6)	01 Sep 2020 04:26:16

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'breaths/min'	System	31 Dec 2020 17:53:35
User entered empty.	System	30 Dec 2020 18:40:09
User entered 'breaths/min'	System	01 Sep 2020 04:26:16

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	31 Dec 2020 17:53:35
User closed query 'Data is required. Please provide.' (Site from System).	Kevin Martinez (b) (4)	31 Dec 2020 13:32:54
Query 'Data is required. Please provide.' answered with 'not done' (Site from System).	(b) (4), (b) (6)	31 Dec 2020 13:32:54
User opened query 'Data is required. Please provide.' (Site from System).	Kevin Martinez (b) (4)	30 Dec 2020 18:40:29
User entered empty; reason for change Data Entry Error	(b) (4)	30 Dec 2020 18:40:09
User entered missing code ND - Not Done.	System	30 Dec 2020 18:40:09
	Kevin Martinez (b) (4)	30 Dec 2020 18:40:09
	(b) (4)	30 Dec 2020 18:40:09
	(b) (4), (b) (6)	01 Sep 2020 04:26:16

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'mmHg'	System	31 Dec 2020 17:53:35
User entered empty.	System	30 Dec 2020 18:40:09
User entered 'mmHg'	System	01 Sep 2020 04:26:16

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	31 Dec 2020 17:53:35
User closed query 'Data is required. Please provide.' (Site from System).	Kevin Martinez (b) (4)	31 Dec 2020 13:32:56
Query 'Data is required. Please provide.' answered with 'not done' (Site from System).	(b) (4), (b) (6)	31 Dec 2020 13:32:56
User opened query 'Data is required. Please provide.' (Site from System).	Kevin Martinez (b) (4)	30 Dec 2020 18:40:22
User entered empty; reason for change Data Entry Error	(b) (4)	30 Dec 2020 18:40:09
User entered missing code ND - Not Done.	System	30 Dec 2020 18:40:09
	Kevin Martinez (b) (4)	30 Dec 2020 18:40:09
	(b) (4)	30 Dec 2020 18:40:09
	(b) (4), (b) (6)	01 Sep 2020 04:26:16

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'mmHg'	System	31 Dec 2020 17:53:35
User entered empty.	System	30 Dec 2020 18:40:09
User entered 'mmHg'	System	01 Sep 2020 04:26:16

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29

US3292365

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:27:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 04:24:29

US3292365

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:27:54

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '29 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 04:24:29

US3292365

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:27:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '29 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 04:24:16

US3292365

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:27:54

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:24:16

US3292365

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:27:54

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:24:16

US3292365

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:27:54

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:24:16

US3292365

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:27:54

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:24:16

US3292365

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:27:54

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:24:16

US3292365

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:27:54

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'un UNK 2014'	(b) (4), (b) (6)	01 Sep 2020 04:24:16

US3292365

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:27:54

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:24:16

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:54

[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 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:54

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 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:54

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 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:54

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 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:54

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 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:54

[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 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:54

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 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:54

[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 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:54

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 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:54

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 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:54

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 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:54

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:54

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'frequent grocery store, gyms with high customer volume'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:54

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:54

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:54

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 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:54

[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 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:54

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 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:54

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'l'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:54

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:54

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:27:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 04:25:28

US3292365

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '29 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 04:25:28

US3292365

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	01 Sep 2020 04:25:28

US3292365

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:27:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered 'VISIT1'	System	01 Sep 2020 04:25:28

US3292365

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '29 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 17:40:36

US3292365

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:27:54

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '109997'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 17:40:36

US3292365

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:27:54

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 17:40:36

US3292365

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:27:54

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:25:18

US3292365

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:27:54

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:25:18

US3292365

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:27:54

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:25:18

US3292365

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:27:54

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:25:18

US3292365

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:27:54

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:25:18

US3292365

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:27:54

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 16:37:12
Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'updated' (Site from DM).	Dawn Killian (b) (4) (b) (4)	07 Dec 2020 23:03:46
User entered 'No (N)'	Dawn Killian (b) (4) (b) (4)	07 Dec 2020 23:03:40
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:48:12
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:36:52
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:36:51

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:27:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:27:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:27:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:27:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User accepted default value 'Pre-Dose (PREDOSE)'		01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '29 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '11:21'	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered '29 Aug 2020 11:21'	System	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '36.7' C	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Oral (Oral)'	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '57'	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered 'bpm'	System	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '12'	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered 'breaths/min'	System	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '143'	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered 'mmHg'	System	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:54

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '88'	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered 'mmHg'	System	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:27:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:27:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '29 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '13:16'	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered '29 Aug 2020 13:16'	System	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '36.8' C	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Oral (Oral)'	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '61'	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered 'bpm'	System	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '16'	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered 'breaths/min'	System	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '140'	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered 'mmHg'	System	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '89'	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered 'mmHg'	System	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:27:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:28:44

US3292365

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:27:54

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:28:44

US3292365

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:27:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 18:21:38

US3292365

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:27:54

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:21:38

US3292365

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:21:38

US3292365

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:27:54

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered 'MRNA-1273 OR PLACEBO'	System	29 Aug 2020 18:21:38

US3292365

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:27:54

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '29 Aug 2020'	(b) (4), (b) (6)	29 Aug 2020 18:21:38

US3292365

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:27:54

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '12:45'	(b) (4), (b) (6)	29 Aug 2020 18:21:38

US3292365

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:27:54

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered '29 Aug 2020 12:45'	System	29 Aug 2020 18:21:38

US3292365

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:27:54

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Right Arm (RIGHT ARM)'	(b) (4), (b) (6)	29 Aug 2020 18:21:38

US3292365

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:27:54

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered 'ONCE'	System	29 Aug 2020 18:21:38

US3292365

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:27:54

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered 'INTRAMUSCULAR'	System	29 Aug 2020 18:21:38

US3292365

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 04:28:09

US3292365

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:54

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '29 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 04:28:09

US3292365

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:54

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '11:35'	(b) (4), (b) (6)	01 Sep 2020 04:28:09

US3292365

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered '29 Aug 2020 11:35'	System	01 Sep 2020 04:28:09

US3292365

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:27:54

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '29 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 04:28:30

US3292365

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:27:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		01 Sep 2020 04:28:30

US3292365

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:27:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 04:28:30

US3292365

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:27:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '11:50'	(b) (4), (b) (6)	01 Sep 2020 04:28:30

US3292365

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:27:54

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered '29 Aug 2020 11:50'	System	01 Sep 2020 04:28:30

US3292365

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:27:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		01 Sep 2020 04:28:30

US3292365

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:27:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:28:30

US3292365

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:27:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:28:30

US3292365

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:27:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered empty.	System	01 Sep 2020 04:28:30

US3292365

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:27:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 04:28:36

US3292365

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:27:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered 'I'	System	01 Sep 2020 04:28:36

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T13:22:16', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '5a75ecce-62cf-4058-ba2a-f244ddab5562'	System	29 Aug 2020 18:22:53
User entered 'Yes (Y)'	System	29 Aug 2020 18:22:53

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T13:22:33', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '5a75ecce-62cf-4058-ba2a-f244ddab5562'	System	29 Aug 2020 18:22:53
User entered '98.2'	System	29 Aug 2020 18:22:53

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T13:22:43', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '5a75ecce-62cf-4058-ba2a-f244ddab5562'	System	29 Aug 2020 18:22:53
User entered 'No (N)'	System	29 Aug 2020 18:22:53

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T13:22:50', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '5a75ecce-62cf-4058-ba2a-f244ddab5562'	System	29 Aug 2020 18:22:53
User entered '29 Aug 2020 13:22'	System	29 Aug 2020 18:22:53

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '29 Aug 2020 13:05'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '29 Aug 2020 15:35'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T20:54:33', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'b9a76140-cabe-4bad-ba85-a80d1c5ef452'	System	30 Aug 2020 01:55:52
User entered 'Yes (Y)'	System	30 Aug 2020 01:55:52

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T20:55:31', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'b9a76140-cabe-4bad-ba85-a80d1c5ef452'	System	30 Aug 2020 01:55:52
User entered '97.2'	System	30 Aug 2020 01:55:52

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T20:55:35', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'b9a76140-cabe-4bad-ba85-a80d1c5ef452'	System	30 Aug 2020 01:55:52
User entered 'No (N)'	System	30 Aug 2020 01:55:52

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T20:55:50', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'b9a76140-cabe-4bad-ba85-a80d1c5ef452'	System	30 Aug 2020 01:55:52
User entered '29 Aug 2020 20:55'	System	30 Aug 2020 01:55:52

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '29 Aug 2020 16:30'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 2'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-30T21:32:53', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '62c31202-31d8-42f4-8b61-38f2b8ec30e8'	System	31 Aug 2020 02:33:09
User entered 'Yes (Y)'	System	31 Aug 2020 02:33:09

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-30T21:32:59', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '62c31202-31d8-42f4-8b61-38f2b8ec30e8'	System	31 Aug 2020 02:33:09
User entered '97.8'	System	31 Aug 2020 02:33:09

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-30T21:33:01', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '62c31202-31d8-42f4-8b61-38f2b8ec30e8'	System	31 Aug 2020 02:33:09
User entered 'No (N)'	System	31 Aug 2020 02:33:09

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-30T21:33:06', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '62c31202-31d8-42f4-8b61-38f2b8ec30e8'	System	31 Aug 2020 02:33:09
User entered '30 Aug 2020 21:33'	System	31 Aug 2020 02:33:09

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 3'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-31T21:06:51', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'd246e6ed-06c0-424e-948a-5697a8a6996b'	System	01 Sep 2020 02:07:08
User entered 'Yes (Y)'	System	01 Sep 2020 02:07:08

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-31T21:06:58', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'd246e6ed-06c0-424e-948a-5697a8a6996b' User entered '96.5'	System	01 Sep 2020 02:07:08
	System	01 Sep 2020 02:07:08

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-31T21:07:01', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'd246e6ed-06c0-424e-948a-5697a8a6996b'	System	01 Sep 2020 02:07:08
User entered 'No (N)'	System	01 Sep 2020 02:07:08

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-31T21:07:05', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'd246e6ed-06c0-424e-948a-5697a8a6996b'	System	01 Sep 2020 02:07:08
User entered '31 Aug 2020 21:07'	System	01 Sep 2020 02:07:08

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 4'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-01T21:04:50', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'ccd45752-0fa3-4db4-9235-900125d0d548'	System	02 Sep 2020 02:06:50
User entered 'Yes (Y)'	System	02 Sep 2020 02:06:50

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-01T21:06:39', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'ccd45752-0fa3-4db4-9235-900125d0d548'	System	02 Sep 2020 02:06:50
User entered '97.9'	System	02 Sep 2020 02:06:50

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-01T21:06:43', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'ccd45752-0fa3-4db4-9235-900125d0d548'	System	02 Sep 2020 02:06:50
User entered 'No (N)'	System	02 Sep 2020 02:06:50

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-01T21:06:47', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'ccd45752-0fa3-4db4-9235-900125d0d548'	System	02 Sep 2020 02:06:50
User entered '01 Sep 2020 21:06'	System	02 Sep 2020 02:06:50

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 5'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-02T21:48:19', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '002038dd-10b6-4634-aa99-e4479cc63153'	System	03 Sep 2020 02:48:44
User entered 'Yes (Y)'	System	03 Sep 2020 02:48:44

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-02T21:48:28', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '002038dd-10b6-4634-aa99-e4479cc63153'	System	03 Sep 2020 02:48:44
User entered '96.9'	System	03 Sep 2020 02:48:44

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-02T21:48:33', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '002038dd-10b6-4634-aa99-e4479cc63153'	System	03 Sep 2020 02:48:44
User entered 'No (N)'	System	03 Sep 2020 02:48:44

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-02T21:48:41', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '002038dd-10b6-4634-aa99-e4479cc63153'	System	03 Sep 2020 02:48:44
User entered '02 Sep 2020 21:48'	System	03 Sep 2020 02:48:44

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 6'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-03T21:04:32', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '0f488190-ad3e-4c01-a282-5e3c066aa1c6'	System	04 Sep 2020 02:04:50
User entered 'Yes (Y)'	System	04 Sep 2020 02:04:50

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-03T21:04:40', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '0f488190-ad3e-4c01-a282-5e3c066aa1c6'	System	04 Sep 2020 02:04:50
User entered '97.3'	System	04 Sep 2020 02:04:50

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-03T21:04:43', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '0f488190-ad3e-4c01-a282-5e3c066aa1c6'	System	04 Sep 2020 02:04:50
User entered 'No (N)'	System	04 Sep 2020 02:04:50

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-03T21:04:46', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '0f488190-ad3e-4c01-a282-5e3c066aa1c6'	System	04 Sep 2020 02:04:50
User entered '03 Sep 2020 21:04'	System	04 Sep 2020 02:04:50

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 7'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-04T22:41:15', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '0de0f01a-3164-44ee-a9bb-80b3d027844b'	System	05 Sep 2020 03:41:37
User entered 'Yes (Y)'	System	05 Sep 2020 03:41:37

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-04T22:41:24', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '0de0f01a-3164-44ee-a9bb-80b3d027844b'	System	05 Sep 2020 03:41:37
User entered '97.3'	System	05 Sep 2020 03:41:37

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-04T22:41:28', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '0de0f01a-3164-44ee-a9bb-80b3d027844b'	System	05 Sep 2020 03:41:37
User entered 'No (N)'	System	05 Sep 2020 03:41:37

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-04T22:41:32', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '0de0f01a-3164-44ee-a9bb-80b3d027844b'	System	05 Sep 2020 03:41:37
User entered '04 Sep 2020 22:41'	System	05 Sep 2020 03:41:37

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '04 Sep 2020 12:00'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '05 Sep 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T13:23:03', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '14aab5de-b82d-48a8-8b8b-ddc7725b5a11'	System	29 Aug 2020 18:23:34
User entered 'None (1)'	System	29 Aug 2020 18:23:34

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T13:23:13', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '14aab5de-b82d-48a8-8b8b-ddc7725b5a11'	System	29 Aug 2020 18:23:34
User entered 'No (N)'	System	29 Aug 2020 18:23:34

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T13:23:20', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '14aab5de-b82d-48a8-8b8b-ddc7725b5a11'	System	29 Aug 2020 18:23:34
User entered 'No (N)'	System	29 Aug 2020 18:23:34

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T13:23:23', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '14aab5de-b82d-48a8-8b8b-ddc7725b5a11'	System	29 Aug 2020 18:23:34
User entered 'None (1)'	System	29 Aug 2020 18:23:34

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T13:23:28', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '14aab5de-b82d-48a8-8b8b-ddc7725b5a11'	System	29 Aug 2020 18:23:34
User entered '29 Aug 2020 13:23'	System	29 Aug 2020 18:23:34

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '29 Aug 2020 13:05'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '29 Aug 2020 15:35'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T20:56:08', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'b0e0ffe0-08b9-4ec2-a745-cc261b8d1bbe'	System	30 Aug 2020 01:58:30
User entered 'Does not interfere with activity (2)'	System	30 Aug 2020 01:58:30

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T20:56:18', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'b0e0ffe0-08b9-4ec2-a745-cc261b8d1bbe'	System	30 Aug 2020 01:58:30
User entered 'No (N)'	System	30 Aug 2020 01:58:30

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T20:56:21', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'b0e0ffe0-08b9-4ec2-a745-cc261b8d1bbe'	System	30 Aug 2020 01:58:30
User entered 'Yes (Y)'	System	30 Aug 2020 01:58:30

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

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)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T20:58:11', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'b0e0ffe0-08b9-4ec2-a745-cc261b8d1bbe'	System	30 Aug 2020 01:58:30
User entered '2'	System	30 Aug 2020 01:58:30

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T20:58:16', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'b0e0ffe0-08b9-4ec2-a745-cc261b8d1bbe'	System	30 Aug 2020 01:58:30
User entered 'None (1)'	System	30 Aug 2020 01:58:30

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T20:58:29', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'b0e0ffe0-08b9-4ec2-a745-cc261b8d1bbe'	System	30 Aug 2020 01:58:30
User entered '29 Aug 2020 20:58'	System	30 Aug 2020 01:58:30

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '29 Aug 2020 16:30'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 2'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:54

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-30T21:33:34', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '32a35f4e-ef34-41bc-b308-ad1de1260617'	System	31 Aug 2020 02:39:05
User entered 'Does not interfere with activity (2)'	System	31 Aug 2020 02:39:05

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-30T21:33:38', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '32a35f4e-ef34-41bc-b308-ad1de1260617'	System	31 Aug 2020 02:39:05
User entered 'No (N)'	System	31 Aug 2020 02:39:05

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:54

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-30T21:33:55', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '32a35f4e-ef34-41bc-b308-ad1de1260617'	System	31 Aug 2020 02:39:05
User entered 'Yes (Y)'	System	31 Aug 2020 02:39:05

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:54

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)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-30T21:38:39', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '32a35f4e-ef34-41bc-b308-ad1de1260617'	System	31 Aug 2020 02:39:05
User entered '2'	System	31 Aug 2020 02:39:05

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:54

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-30T21:38:51', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '32a35f4e-ef34-41bc-b308-ad1de1260617'	System	31 Aug 2020 02:39:05
User entered 'None (1)'	System	31 Aug 2020 02:39:05

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-30T21:39:02', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '32a35f4e-ef34-41bc-b308-ad1de1260617'	System	31 Aug 2020 02:39:05
User entered '30 Aug 2020 21:39'	System	31 Aug 2020 02:39:05

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 3'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:54

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-31T21:07:12', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'd5bff098-092a-4eb2-b6e6-18b03e1537d0'	System	01 Sep 2020 02:07:28
User entered 'None (1)'	System	01 Sep 2020 02:07:28

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:54

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-31T21:07:15', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'd5bff098-092a-4eb2-b6e6-18b03e1537d0'	System	01 Sep 2020 02:07:28
User entered 'No (N)'	System	01 Sep 2020 02:07:28

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:54

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-31T21:07:18', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'd5bff098-092a-4eb2-b6e6-18b03e1537d0'	System	01 Sep 2020 02:07:28
User entered 'No (N)'	System	01 Sep 2020 02:07:28

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:54

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-31T21:07:21', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'd5bff098-092a-4eb2-b6e6-18b03e1537d0'	System	01 Sep 2020 02:07:28
User entered 'None (1)'	System	01 Sep 2020 02:07:28

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-31T21:07:26', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'd5bff098-092a-4eb2-b6e6-18b03e1537d0'	System	01 Sep 2020 02:07:28
User entered '31 Aug 2020 21:07'	System	01 Sep 2020 02:07:28

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 4'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:54

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-01T21:06:53', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '038ed6c5-5807-4957-9918-a39e229d728c'	System	02 Sep 2020 02:07:08
User entered 'None (1)'	System	02 Sep 2020 02:07:08

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-01T21:06:56', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '038ed6c5-5807-4957-9918-a39e229d728c'	System	02 Sep 2020 02:07:08
User entered 'No (N)'	System	02 Sep 2020 02:07:08

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:54

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-01T21:06:58', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '038ed6c5-5807-4957-9918-a39e229d728c'	System	02 Sep 2020 02:07:08
User entered 'No (N)'	System	02 Sep 2020 02:07:08

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:54

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-01T21:07:01', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '038ed6c5-5807-4957-9918-a39e229d728c'	System	02 Sep 2020 02:07:08
User entered 'None (1)'	System	02 Sep 2020 02:07:08

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-01T21:07:05', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '038ed6c5-5807-4957-9918-a39e229d728c'	System	02 Sep 2020 02:07:08
User entered '01 Sep 2020 21:07'	System	02 Sep 2020 02:07:08

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 5'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:54

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-02T21:48:46', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '85b8dadd-c791-425f-bb1c-15b0736e7867'	System	03 Sep 2020 02:49:04
User entered 'None (1)'	System	03 Sep 2020 02:49:04

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-02T21:48:49', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '85b8dadd-c791-425f-bb1c-15b0736e7867'	System	03 Sep 2020 02:49:04
User entered 'No (N)'	System	03 Sep 2020 02:49:04

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:54

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-02T21:48:51', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '85b8dadd-c791-425f-bb1c-15b0736e7867'	System	03 Sep 2020 02:49:04
User entered 'No (N)'	System	03 Sep 2020 02:49:04

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:54

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-02T21:48:54', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '85b8dadd-c791-425f-bb1c-15b0736e7867'	System	03 Sep 2020 02:49:04
User entered 'None (1)'	System	03 Sep 2020 02:49:04

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-02T21:49:03', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '85b8dadd-c791-425f-bb1c-15b0736e7867'	System	03 Sep 2020 02:49:04
User entered '02 Sep 2020 21:49'	System	03 Sep 2020 02:49:04

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 6'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:54

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-03T21:04:51', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '535272ef-95b0-416b-a8d2-181caba263a6'	System	04 Sep 2020 02:05:11
User entered 'None (1)'	System	04 Sep 2020 02:05:11

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-03T21:04:54', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '535272ef-95b0-416b-a8d2-181caba263a6'	System	04 Sep 2020 02:05:11
User entered 'No (N)'	System	04 Sep 2020 02:05:11

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:54

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-03T21:04:57', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '535272ef-95b0-416b-a8d2-181caba263a6'	System	04 Sep 2020 02:05:11
User entered 'No (N)'	System	04 Sep 2020 02:05:11

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:54

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-03T21:05:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '535272ef-95b0-416b-a8d2-181caba263a6'	System	04 Sep 2020 02:05:11
User entered 'None (1)'	System	04 Sep 2020 02:05:11

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-03T21:05:07', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '535272ef-95b0-416b-a8d2-181caba263a6'	System	04 Sep 2020 02:05:11
User entered '03 Sep 2020 21:05'	System	04 Sep 2020 02:05:11

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 7'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:54

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-04T22:41:44', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '46c4fb11-78f9-4a61-bd6a-f2ff9b92af06'	System	05 Sep 2020 03:42:01
User entered 'None (1)'	System	05 Sep 2020 03:42:01

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-04T22:41:42', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '46c4fb11-78f9-4a61-bd6a-f2ff9b92af06'	System	05 Sep 2020 03:42:01
User entered 'No (N)'	System	05 Sep 2020 03:42:01

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:54

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-04T22:41:47', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '46c4fb11-78f9-4a61-bd6a-f2ff9b92af06'	System	05 Sep 2020 03:42:01
User entered 'No (N)'	System	05 Sep 2020 03:42:01

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:54

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-04T22:41:51', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '46c4fb11-78f9-4a61-bd6a-f2ff9b92af06'	System	05 Sep 2020 03:42:01
User entered 'None (1)'	System	05 Sep 2020 03:42:01

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-04T22:41:57', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '46c4fb11-78f9-4a61-bd6a-f2ff9b92af06'	System	05 Sep 2020 03:42:01
User entered '04 Sep 2020 22:41'	System	05 Sep 2020 03:42:01

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '04 Sep 2020 12:00'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '05 Sep 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T13:23:33', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'e0d99ad8-4a4b-4800-b8f4-750055dc4bde'	System	29 Aug 2020 18:23:55
User entered 'None (0)'	System	29 Aug 2020 18:23:55

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T13:23:35', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'e0d99ad8-4a4b-4800-b8f4-750055dc4bde'	System	29 Aug 2020 18:23:55
User entered 'None (0)'	System	29 Aug 2020 18:23:55

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T13:23:38', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'e0d99ad8-4a4b-4800-b8f4-750055dc4bde'	System	29 Aug 2020 18:23:55
User entered 'None (0)'	System	29 Aug 2020 18:23:55

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T13:23:40', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'e0d99ad8-4a4b-4800-b8f4-750055dc4bde'	System	29 Aug 2020 18:23:55
User entered 'None (0)'	System	29 Aug 2020 18:23:55

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T13:23:42', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'e0d99ad8-4a4b-4800-b8f4-750055dc4bde'	System	29 Aug 2020 18:23:55
User entered 'None (0)'	System	29 Aug 2020 18:23:55

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T13:23:44', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'e0d99ad8-4a4b-4800-b8f4-750055dc4bde'	System	29 Aug 2020 18:23:55
User entered 'None (0)'	System	29 Aug 2020 18:23:55

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

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)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T13:23:49', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'e0d99ad8-4a4b-4800-b8f4-750055dc4bde'	System	29 Aug 2020 18:23:55
User entered 'No (N)'	System	29 Aug 2020 18:23:55

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T13:23:52', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'e0d99ad8-4a4b-4800-b8f4-750055dc4bde'	System	29 Aug 2020 18:23:55
User entered '29 Aug 2020 13:23'	System	29 Aug 2020 18:23:55

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '29 Aug 2020 13:05'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '29 Aug 2020 15:35'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T20:58:34', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '24086eb7-170a-4bfd-87c2-3fde52ca9d5a'	System	30 Aug 2020 01:59:01
User entered 'None (0)'	System	30 Aug 2020 01:59:01

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T20:58:37', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '24086eb7-170a-4bfd-87c2-3fde52ca9d5a'	System	30 Aug 2020 01:59:01
User entered 'None (0)'	System	30 Aug 2020 01:59:01

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T20:58:40', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '24086eb7-170a-4bfd-87c2-3fde52ca9d5a'	System	30 Aug 2020 01:59:01
User entered 'None (0)'	System	30 Aug 2020 01:59:01

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T20:58:42', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '24086eb7-170a-4bfd-87c2-3fde52ca9d5a'	System	30 Aug 2020 01:59:01
User entered 'None (0)'	System	30 Aug 2020 01:59:01

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T20:58:44', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '24086eb7-170a-4bfd-87c2-3fde52ca9d5a'	System	30 Aug 2020 01:59:01
User entered 'None (0)'	System	30 Aug 2020 01:59:01

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T20:58:46', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '24086eb7-170a-4bfd-87c2-3fde52ca9d5a'	System	30 Aug 2020 01:59:01
User entered 'None (0)'	System	30 Aug 2020 01:59:01

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

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)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T20:58:51', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '24086eb7-170a-4bfd-87c2-3fde52ca9d5a'	System	30 Aug 2020 01:59:01
User entered 'No (N)'	System	30 Aug 2020 01:59:01

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T20:58:56', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '24086eb7-170a-4bfd-87c2-3fde52ca9d5a'	System	30 Aug 2020 01:59:01
User entered '29 Aug 2020 20:58'	System	30 Aug 2020 01:59:01

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '29 Aug 2020 16:30'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 2'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-30T21:39:09', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '2ec36d36-4324-482a-a0e5-2e73a0e3719b'	System	31 Aug 2020 02:39:35
User entered 'None (0)'	System	31 Aug 2020 02:39:35

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-30T21:39:12', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '2ec36d36-4324-482a-a0e5-2e73a0e3719b'	System	31 Aug 2020 02:39:35
User entered 'None (0)'	System	31 Aug 2020 02:39:35

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-30T21:39:14', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '2ec36d36-4324-482a-a0e5-2e73a0e3719b'	System	31 Aug 2020 02:39:35
User entered 'None (0)'	System	31 Aug 2020 02:39:35

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-30T21:39:16', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '2ec36d36-4324-482a-a0e5-2e73a0e3719b'	System	31 Aug 2020 02:39:35
User entered 'None (0)'	System	31 Aug 2020 02:39:35

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-30T21:39:18', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '2ec36d36-4324-482a-a0e5-2e73a0e3719b'	System	31 Aug 2020 02:39:35
User entered 'None (0)'	System	31 Aug 2020 02:39:35

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-30T21:39:21', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '2ec36d36-4324-482a-a0e5-2e73a0e3719b'	System	31 Aug 2020 02:39:35
User entered 'None (0)'	System	31 Aug 2020 02:39:35

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:54

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)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-30T21:39:25', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '2ec36d36-4324-482a-a0e5-2e73a0e3719b'	System	31 Aug 2020 02:39:35
User entered 'No (N)'	System	31 Aug 2020 02:39:35

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-30T21:39:32', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '2ec36d36-4324-482a-a0e5-2e73a0e3719b'	System	31 Aug 2020 02:39:35
User entered '30 Aug 2020 21:39'	System	31 Aug 2020 02:39:35

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 3'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-31T21:07:32', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '409d7d8d-4ea6-4e19-810d-6c6a666c551e'	System	01 Sep 2020 02:07:53
User entered 'None (0)'	System	01 Sep 2020 02:07:53

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-31T21:07:35', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '409d7d8d-4ea6-4e19-810d-6c6a666c551e'	System	01 Sep 2020 02:07:53
User entered 'None (0)'	System	01 Sep 2020 02:07:53

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-31T21:07:38', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '409d7d8d-4ea6-4e19-810d-6c6a666c551e'	System	01 Sep 2020 02:07:53
User entered 'None (0)'	System	01 Sep 2020 02:07:53

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-31T21:07:40', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '409d7d8d-4ea6-4e19-810d-6c6a666c551e'	System	01 Sep 2020 02:07:53
User entered 'None (0)'	System	01 Sep 2020 02:07:53

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-31T21:07:42', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '409d7d8d-4ea6-4e19-810d-6c6a666c551e'	System	01 Sep 2020 02:07:53
User entered 'None (0)'	System	01 Sep 2020 02:07:53

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-31T21:07:44', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '409d7d8d-4ea6-4e19-810d-6c6a666c551e'	System	01 Sep 2020 02:07:53
User entered 'None (0)'	System	01 Sep 2020 02:07:53

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:54

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)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-31T21:07:47', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '409d7d8d-4ea6-4e19-810d-6c6a666c551e'	System	01 Sep 2020 02:07:53
User entered 'No (N)'	System	01 Sep 2020 02:07:53

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-31T21:07:50', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '409d7d8d-4ea6-4e19-810d-6c6a666c551e'	System	01 Sep 2020 02:07:53
User entered '31 Aug 2020 21:07'	System	01 Sep 2020 02:07:53

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 4'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-01T21:07:09', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '463e8178-0dce-44f6-92e8-214eb8317ab3'	System	02 Sep 2020 02:07:28
User entered 'None (0)'	System	02 Sep 2020 02:07:28

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-01T21:07:11', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '463e8178-0dce-44f6-92e8-214eb8317ab3'	System	02 Sep 2020 02:07:28
User entered 'None (0)'	System	02 Sep 2020 02:07:28

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-01T21:07:13', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '463e8178-0dce-44f6-92e8-214eb8317ab3'	System	02 Sep 2020 02:07:28
User entered 'None (0)'	System	02 Sep 2020 02:07:28

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-01T21:07:15', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '463e8178-0dce-44f6-92e8-214eb8317ab3'	System	02 Sep 2020 02:07:28
User entered 'None (0)'	System	02 Sep 2020 02:07:28

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-01T21:07:17', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '463e8178-0dce-44f6-92e8-214eb8317ab3'	System	02 Sep 2020 02:07:28
User entered 'None (0)'	System	02 Sep 2020 02:07:28

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-01T21:07:18', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '463e8178-0dce-44f6-92e8-214eb8317ab3'	System	02 Sep 2020 02:07:28
User entered 'None (0)'	System	02 Sep 2020 02:07:28

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:54

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)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-01T21:07:21', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '463e8178-0dce-44f6-92e8-214eb8317ab3'	System	02 Sep 2020 02:07:28
User entered 'No (N)'	System	02 Sep 2020 02:07:28

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-01T21:07:25', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '463e8178-0dce-44f6-92e8-214eb8317ab3'	System	02 Sep 2020 02:07:28
User entered '01 Sep 2020 21:07'	System	02 Sep 2020 02:07:28

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 5'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-02T21:49:08', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '720c6602-41d1-46f4-bab5-adf0d0c410e9'	System	03 Sep 2020 02:49:28
User entered 'None (0)'	System	03 Sep 2020 02:49:28

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-02T21:49:11', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '720c6602-41d1-46f4-bab5-adf0d0c410e9'	System	03 Sep 2020 02:49:28
User entered 'None (0)'	System	03 Sep 2020 02:49:28

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-02T21:49:13', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '720c6602-41d1-46f4-bab5-adf0d0c410e9'	System	03 Sep 2020 02:49:28
User entered 'None (0)'	System	03 Sep 2020 02:49:28

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-02T21:49:17', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '720c6602-41d1-46f4-bab5-adf0d0c410e9'	System	03 Sep 2020 02:49:28
User entered 'None (0)'	System	03 Sep 2020 02:49:28

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-02T21:49:19', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '720c6602-41d1-46f4-bab5-adf0d0c410e9'	System	03 Sep 2020 02:49:28
User entered 'None (0)'	System	03 Sep 2020 02:49:28

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-02T21:49:21', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '720c6602-41d1-46f4-bab5-adf0d0c410e9'	System	03 Sep 2020 02:49:28
User entered 'None (0)'	System	03 Sep 2020 02:49:28

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:54

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)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-02T21:49:24', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '720c6602-41d1-46f4-bab5-adf0d0c410e9'	System	03 Sep 2020 02:49:28
User entered 'No (N)'	System	03 Sep 2020 02:49:28

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-02T21:49:27', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '720c6602-41d1-46f4-bab5-adf0d0c410e9'	System	03 Sep 2020 02:49:28
User entered '02 Sep 2020 21:49'	System	03 Sep 2020 02:49:28

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 6'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-03T21:05:13', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'fc9c62e0-da92-4dc1-ac5c-b463649e334c'	System	04 Sep 2020 02:05:36
User entered 'None (0)'	System	04 Sep 2020 02:05:36

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-03T21:05:16', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'fc9c62e0-da92-4dc1-ac5c-b463649e334c'	System	04 Sep 2020 02:05:36
User entered 'None (0)'	System	04 Sep 2020 02:05:36

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-03T21:05:18', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'fc9c62e0-da92-4dc1-ac5c-b463649e334c'	System	04 Sep 2020 02:05:36
User entered 'None (0)'	System	04 Sep 2020 02:05:36

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-03T21:05:20', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'fc9c62e0-da92-4dc1-ac5c-b463649e334c'	System	04 Sep 2020 02:05:36
User entered 'None (0)'	System	04 Sep 2020 02:05:36

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-03T21:05:23', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'fc9c62e0-da92-4dc1-ac5c-b463649e334c'	System	04 Sep 2020 02:05:36
User entered 'None (0)'	System	04 Sep 2020 02:05:36

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-03T21:05:25', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'fc9c62e0-da92-4dc1-ac5c-b463649e334c'	System	04 Sep 2020 02:05:36
User entered 'None (0)'	System	04 Sep 2020 02:05:36

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:54

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)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-03T21:05:30', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'fc9c62e0-da92-4dc1-ac5c-b463649e334c'	System	04 Sep 2020 02:05:36
User entered 'No (N)'	System	04 Sep 2020 02:05:36

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-03T21:05:34', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'fc9c62e0-da92-4dc1-ac5c-b463649e334c'	System	04 Sep 2020 02:05:36
User entered '03 Sep 2020 21:05'	System	04 Sep 2020 02:05:36

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 7'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-04T22:42:03', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'af8a7b9a-0593-4d05-9e8d-05ed126d431b'	System	05 Sep 2020 03:42:22
User entered 'None (0)'	System	05 Sep 2020 03:42:22

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-04T22:42:05', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'af8a7b9a-0593-4d05-9e8d-05ed126d431b'	System	05 Sep 2020 03:42:22
User entered 'None (0)'	System	05 Sep 2020 03:42:22

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-04T22:42:07', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'af8a7b9a-0593-4d05-9e8d-05ed126d431b'	System	05 Sep 2020 03:42:22
User entered 'None (0)'	System	05 Sep 2020 03:42:22

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-04T22:42:09', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'af8a7b9a-0593-4d05-9e8d-05ed126d431b'	System	05 Sep 2020 03:42:22
User entered 'None (0)'	System	05 Sep 2020 03:42:22

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-04T22:42:11', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'af8a7b9a-0593-4d05-9e8d-05ed126d431b'	System	05 Sep 2020 03:42:22
User entered 'None (0)'	System	05 Sep 2020 03:42:22

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-04T22:42:13', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'af8a7b9a-0593-4d05-9e8d-05ed126d431b'	System	05 Sep 2020 03:42:22
User entered 'None (0)'	System	05 Sep 2020 03:42:22

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:54

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)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-04T22:42:17', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'af8a7b9a-0593-4d05-9e8d-05ed126d431b'	System	05 Sep 2020 03:42:22
User entered 'No (N)'	System	05 Sep 2020 03:42:22

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-04T22:42:19', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'af8a7b9a-0593-4d05-9e8d-05ed126d431b'	System	05 Sep 2020 03:42:22
User entered '04 Sep 2020 22:42'	System	05 Sep 2020 03:42:22

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '04 Sep 2020 12:00'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '05 Sep 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	08 Sep 2020 20:47:41

US3292365

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '8 Sep 2020'	(b) (4) Kristy Trevino (b) (4)	08 Sep 2020 20:47:41

US3292365

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kristy Trevino (b) (4)	08 Sep 2020 20:47:41

US3292365

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4) Kristy Trevino (b) (4)	08 Sep 2020 20:47:41

US3292365

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	08 Sep 2020 20:47:46

US3292365

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered 'l'	System	08 Sep 2020 20:47:46

US3292365

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:56:57
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	15 Sep 2020 18:23:24

US3292365

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:56:57
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '15 Sep 2020'	(b) (4) Kristy Trevino (b) (4)	15 Sep 2020 18:23:24

US3292365

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:56:57
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kristy Trevino (b) (4)	15 Sep 2020 18:23:24

US3292365

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:56:57
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4) Kristy Trevino (b) (4) (b) (4)	15 Sep 2020 18:23:24

US3292365

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:56:57
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	15 Sep 2020 18:23:56

US3292365

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:56:57
User entered 'l'	System	15 Sep 2020 18:23:56

US3292365

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 20:02:12

US3292365

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 20:02:12

US3292365

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Sep 2020 20:02:12

US3292365

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 20:02:12

US3292365

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:56:57
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 20:02:16

US3292365

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:56:57
User entered 'l'	System	22 Sep 2020 20:02:16

US3292365

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 17:00:42

US3292365

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:54

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '26 Sep 2020'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 17:00:42

US3292365

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:54

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	26 Sep 2020 17:00:42

US3292365

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered 'VISIT2'	System	26 Sep 2020 17:00:42

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User accepted default value 'Pre-Dose (PREDOSE)'		26 Sep 2020 17:02:03

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 17:02:03

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '26 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 17:02:03

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:54

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '08:45'	(b) (4), (b) (6)	26 Sep 2020 17:02:03

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered '26 Sep 2020 08:45'	System	26 Sep 2020 17:02:03

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '36.5' C	(b) (4), (b) (6)	26 Sep 2020 17:02:03

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Oral (Oral)'	(b) (4), (b) (6)	26 Sep 2020 17:02:03

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 17:02:03

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '61'	(b) (4), (b) (6)	26 Sep 2020 17:02:03

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered 'bpm'	System	26 Sep 2020 17:02:03

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '16'	(b) (4), (b) (6)	26 Sep 2020 17:02:03

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered 'breaths/min'	System	26 Sep 2020 17:02:03

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '127'	(b) (4), (b) (6)	26 Sep 2020 17:02:03

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered 'mmHg'	System	26 Sep 2020 17:02:03

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:54

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '81'	(b) (4), (b) (6)	26 Sep 2020 17:02:03

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered 'mmHg'	System	26 Sep 2020 17:02:03

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User accepted default value 'Post-Dose (POSTDOSE)'		26 Sep 2020 17:02:49

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 17:02:49

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '26 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 17:02:49

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:54

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '10:14'	(b) (4), (b) (6)	26 Sep 2020 17:02:49

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered '26 Sep 2020 10:14'	System	26 Sep 2020 17:02:49

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '36.6' C	(b) (4), (b) (6)	26 Sep 2020 17:02:49

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Oral (Oral)'	(b) (4), (b) (6)	26 Sep 2020 17:02:49

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 17:02:49

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '56'	(b) (4), (b) (6)	26 Sep 2020 17:02:49

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered 'bpm'	System	26 Sep 2020 17:02:49

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '16'	(b) (4), (b) (6)	26 Sep 2020 17:02:49

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered 'breaths/min'	System	26 Sep 2020 17:02:49

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '138'	(b) (4), (b) (6)	26 Sep 2020 17:02:49

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered 'mmHg'	System	26 Sep 2020 17:02:49

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '87'	(b) (4), (b) (6)	26 Sep 2020 17:02:49

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered 'mmHg'	System	26 Sep 2020 17:02:49

US3292365

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:27:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 17:00:49

US3292365

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:27:54

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '26 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 17:00:49

US3292365

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	26 Sep 2020 15:15:38

US3292365

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:54

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4) Nathan Cortez (b) (4)	26 Sep 2020 15:15:38

US3292365

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:54

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4) Nathan Cortez (b) (4)	26 Sep 2020 15:15:38

US3292365

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:54

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered 'MRNA-1273 OR PLACEBO'	System	26 Sep 2020 15:15:38

US3292365

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:54

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '26 Sep 2020'	(b) (4) Nathan Cortez (b) (4)	26 Sep 2020 15:15:38

US3292365

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:54

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '09:42'	(b) (4) Nathan Cortez (b) (4)	26 Sep 2020 15:15:38

US3292365

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:54

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered '26 Sep 2020 09:42'	System	26 Sep 2020 15:15:38

US3292365

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:54

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Nathan Cortez (b) (4)	26 Sep 2020 15:15:38

US3292365

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:54

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered 'ONCE'	System	26 Sep 2020 15:15:38

US3292365

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:54

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered 'INTRAMUSCULAR'	System	26 Sep 2020 15:15:38

US3292365

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 17:01:04

US3292365

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:54

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '26 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 17:01:04

US3292365

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:54

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '08:53'	(b) (4), (b) (6)	26 Sep 2020 17:01:04

US3292365

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered '26 Sep 2020 08:53'	System	26 Sep 2020 17:01:04

US3292365

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:27:54

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '26 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 17:01:23

US3292365

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:27:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	26 Sep 2020 17:01:23

US3292365

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:27:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 17:01:23

US3292365

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:27:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '09:09'	(b) (4), (b) (6)	26 Sep 2020 17:01:23

US3292365

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:27:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered '26 Sep 2020 09:09'	System	26 Sep 2020 17:01:23

US3292365

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:27:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		26 Sep 2020 17:01:23

US3292365

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:27:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 17:01:23

US3292365

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:27:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 17:01:23

US3292365

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:27:54

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered empty.	System	26 Sep 2020 17:01:23

US3292365

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 17:01:27

US3292365

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered 'I'	System	26 Sep 2020 17:01:27

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T10:17:33', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f45b8eaf-17cb-4e04-97cf-5ba9178c9942'	System	26 Sep 2020 15:17:59
User entered 'Yes (Y)'	System	26 Sep 2020 15:17:59

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T10:17:39', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f45b8eaf-17cb-4e04-97cf-5ba9178c9942'	System	26 Sep 2020 15:17:59
User entered '97.8'	System	26 Sep 2020 15:17:59

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T10:17:49', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f45b8eaf-17cb-4e04-97cf-5ba9178c9942'	System	26 Sep 2020 15:17:59
User entered 'No (N)'	System	26 Sep 2020 15:17:59

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T10:17:57', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f45b8eaf-17cb-4e04-97cf-5ba9178c9942'	System	26 Sep 2020 15:17:59
User entered '26 Sep 2020 10:17'	System	26 Sep 2020 15:17:59

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '26 Sep 2020 10:02'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '26 Sep 2020 12:32'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 1, after vaccination (at home)'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T21:30:57', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'dbbfcfb2-efb-4f5b-9dad-1a78d30ca278'	System	27 Sep 2020 02:32:01
User entered 'Yes (Y)'	System	27 Sep 2020 02:32:01

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T21:31:46', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'dbbfcfb2-efb-4f5b-9dad-1a78d30ca278'	System	27 Sep 2020 02:32:01
User entered '96.4'	System	27 Sep 2020 02:32:01

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T21:31:48', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'dbbfcfb2-efb-4f5b-9dad-1a78d30ca278'	System	27 Sep 2020 02:32:01
User entered 'No (N)'	System	27 Sep 2020 02:32:01

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T21:31:58', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'dbbfcfb2-efb-4f5b-9dad-1a78d30ca278'	System	27 Sep 2020 02:32:01
User entered '26 Sep 2020 21:31'	System	27 Sep 2020 02:32:01

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '26 Sep 2020 13:27'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '27 Sep 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 2'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-27T21:03:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '45453b71-5042-4295-b816-d53432b925dc'	System	28 Sep 2020 02:03:23
User entered 'Yes (Y)'	System	28 Sep 2020 02:03:23

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-27T21:03:06', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '45453b71-5042-4295-b816-d53432b925dc' User entered '100.5'	System	28 Sep 2020 02:03:23
	System	28 Sep 2020 02:03:23

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:54

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-27T21:03:11', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '45453b71-5042-4295-b816-d53432b925dc'	System	28 Sep 2020 02:03:23
User entered 'No (N)'	System	28 Sep 2020 02:03:23

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-27T21:03:22', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '45453b71-5042-4295-b816-d53432b925dc'	System	28 Sep 2020 02:03:23
User entered '27 Sep 2020 21:03'	System	28 Sep 2020 02:03:23

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 3'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-28T20:56:39', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f64c688f-e17d-462b-b810-25e8dc6aebcb'	System	29 Sep 2020 01:56:57
User entered 'Yes (Y)'	System	29 Sep 2020 01:56:57

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-28T20:56:46', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f64c688f-e17d-462b-b810-25e8dc6aebcb'	System	29 Sep 2020 01:56:57
User entered '97.5'	System	29 Sep 2020 01:56:57

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:54

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-28T20:56:49', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f64c688f-e17d-462b-b810-25e8dc6aebcb'	System	29 Sep 2020 01:56:57
User entered 'No (N)'	System	29 Sep 2020 01:56:57

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-28T20:56:54', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f64c688f-e17d-462b-b810-25e8dc6aebcb'	System	29 Sep 2020 01:56:57
User entered '28 Sep 2020 20:56'	System	29 Sep 2020 01:56:57

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 4'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-29T22:31:35', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '17ba10dd-5fd7-4bdf-bcfa-a5d12673d4f3'	System	30 Sep 2020 03:31:53
User entered 'Yes (Y)'	System	30 Sep 2020 03:31:53

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-29T22:31:41', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '17ba10dd-5fd7-4bdf-bcfa-a5d12673d4f3'	System	30 Sep 2020 03:31:53
User entered '97.6'	System	30 Sep 2020 03:31:53

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:54

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-29T22:31:44', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '17ba10dd-5fd7-4bdf-bcfa-a5d12673d4f3'	System	30 Sep 2020 03:31:53
User entered 'No (N)'	System	30 Sep 2020 03:31:53

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-29T22:31:50', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '17ba10dd-5fd7-4bdf-bcfa-a5d12673d4f3'	System	30 Sep 2020 03:31:53
User entered '29 Sep 2020 22:31'	System	30 Sep 2020 03:31:53

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '29 Sep 2020 12:00'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '30 Sep 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 5'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-30T22:21:09', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '43ebe4ba-7cad-40a8-b80c-266a81f67674'	System	01 Oct 2020 03:22:55
User entered 'Yes (Y)'	System	01 Oct 2020 03:22:55

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-30T22:22:46', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '43ebe4ba-7cad-40a8-b80c-266a81f67674'	System	01 Oct 2020 03:22:55
User entered '97.1'	System	01 Oct 2020 03:22:55

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:54

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-30T22:22:49', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '43ebe4ba-7cad-40a8-b80c-266a81f67674'	System	01 Oct 2020 03:22:55
User entered 'No (N)'	System	01 Oct 2020 03:22:55

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-30T22:22:53', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '43ebe4ba-7cad-40a8-b80c-266a81f67674'	System	01 Oct 2020 03:22:55
User entered '30 Sep 2020 22:22'	System	01 Oct 2020 03:22:55

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '30 Sep 2020 12:00'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '01 Oct 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 6'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-01T20:37:23', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'cba51f93-33b1-4705-ab79-544520d3f4f3'	System	02 Oct 2020 01:37:50
User entered 'Yes (Y)'	System	02 Oct 2020 01:37:50

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-01T20:37:30', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'cba51f93-33b1-4705-ab79-544520d3f4f3'	System	02 Oct 2020 01:37:50
User entered '98.0'	System	02 Oct 2020 01:37:50

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:54

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-01T20:37:35', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'cba51f93-33b1-4705-ab79-544520d3f4f3'	System	02 Oct 2020 01:37:50
User entered 'No (N)'	System	02 Oct 2020 01:37:50

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-01T20:37:45', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'cba51f93-33b1-4705-ab79-544520d3f4f3'	System	02 Oct 2020 01:37:50
User entered '01 Oct 2020 20:37'	System	02 Oct 2020 01:37:50

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '01 Oct 2020 12:00'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '02 Oct 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 7'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-02T23:26:48', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '66bf52bf-db90-4f33-81dc-44fa954c75d6'	System	03 Oct 2020 04:27:09
User entered 'Yes (Y)'	System	03 Oct 2020 04:27:09

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-02T23:26:55', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '66bf52bf-db90-4f33-81dc-44fa954c75d6'	System	03 Oct 2020 04:27:09
User entered '96.5'	System	03 Oct 2020 04:27:09

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:54

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-02T23:27:02', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '66bf52bf-db90-4f33-81dc-44fa954c75d6'	System	03 Oct 2020 04:27:09
User entered 'No (N)'	System	03 Oct 2020 04:27:09

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-02T23:27:05', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '66bf52bf-db90-4f33-81dc-44fa954c75d6'	System	03 Oct 2020 04:27:09
User entered '02 Oct 2020 23:27'	System	03 Oct 2020 04:27:09

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '02 Oct 2020 12:00'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '03 Oct 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T10:18:12', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '87bc2331-ef5f-4b32-9220-43ae11324efd'	System	26 Sep 2020 15:19:22
User entered 'None (1)'	System	26 Sep 2020 15:19:22

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T10:18:18', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '87bc2331-ef5f-4b32-9220-43ae11324efd'	System	26 Sep 2020 15:19:22
User entered 'No (N)'	System	26 Sep 2020 15:19:22

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T10:19:12', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '87bc2331-ef5f-4b32-9220-43ae11324efd'	System	26 Sep 2020 15:19:22
User entered 'No (N)'	System	26 Sep 2020 15:19:22

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T10:19:15', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '87bc2331-ef5f-4b32-9220-43ae11324efd'	System	26 Sep 2020 15:19:22
User entered 'None (1)'	System	26 Sep 2020 15:19:22

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T10:19:20', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '87bc2331-ef5f-4b32-9220-43ae11324efd'	System	26 Sep 2020 15:19:22
User entered '26 Sep 2020 10:19'	System	26 Sep 2020 15:19:22

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '26 Sep 2020 10:02'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '26 Sep 2020 12:32'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 1, after vaccination (at home)'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T21:32:06', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '7231c723-9ff3-418e-9d30-8308a9b620f2'	System	27 Sep 2020 02:33:01
User entered 'Does not interfere with activity (2)'	System	27 Sep 2020 02:33:01

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T21:32:30', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '7231c723-9ff3-418e-9d30-8308a9b620f2'	System	27 Sep 2020 02:33:01
User entered 'No (N)'	System	27 Sep 2020 02:33:01

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T21:32:50', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '7231c723-9ff3-418e-9d30-8308a9b620f2'	System	27 Sep 2020 02:33:01
User entered 'No (N)'	System	27 Sep 2020 02:33:01

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T21:32:53', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '7231c723-9ff3-418e-9d30-8308a9b620f2'	System	27 Sep 2020 02:33:01
User entered 'None (1)'	System	27 Sep 2020 02:33:01

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T21:32:56', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '7231c723-9ff3-418e-9d30-8308a9b620f2'	System	27 Sep 2020 02:33:01
User entered '26 Sep 2020 21:32'	System	27 Sep 2020 02:33:01

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '26 Sep 2020 13:27'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '27 Sep 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 2'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:54

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-27T21:03:32', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f4623788-2c00-4d87-bae3-42ae606a9fac'	System	28 Sep 2020 02:06:19
User entered 'Does not interfere with activity (2)'	System	28 Sep 2020 02:06:19

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-27T21:05:32', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f4623788-2c00-4d87-bae3-42ae606a9fac'	System	28 Sep 2020 02:06:19
User entered 'Yes (Y)'	System	28 Sep 2020 02:06:19

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:54

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)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-27T21:05:46', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f4623788-2c00-4d87-bae3-42ae606a9fac'	System	28 Sep 2020 02:06:19
User entered '4'	System	28 Sep 2020 02:06:19

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:54

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-27T21:05:49', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f4623788-2c00-4d87-bae3-42ae606a9fac'	System	28 Sep 2020 02:06:19
User entered 'Yes (Y)'	System	28 Sep 2020 02:06:19

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:54

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)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-27T21:05:54', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f4623788-2c00-4d87-bae3-42ae606a9fac'	System	28 Sep 2020 02:06:19
User entered '4'	System	28 Sep 2020 02:06:19

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:54

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-27T21:06:04', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f4623788-2c00-4d87-bae3-42ae606a9fac'	System	28 Sep 2020 02:06:19
User entered 'None (1)'	System	28 Sep 2020 02:06:19

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-27T21:06:17', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f4623788-2c00-4d87-bae3-42ae606a9fac'	System	28 Sep 2020 02:06:19
User entered '27 Sep 2020 21:06'	System	28 Sep 2020 02:06:19

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 3'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:54

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-28T20:57:06', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '255e8603-ca93-489d-8988-9cf12ae7e5ca'	System	29 Sep 2020 02:00:16
User entered 'Does not interfere with activity (2)'	System	29 Sep 2020 02:00:16

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-28T20:57:30', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '255e8603-ca93-489d-8988-9cf12ae7e5ca'	System	29 Sep 2020 02:00:16
User entered 'Yes (Y)'	System	29 Sep 2020 02:00:16

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:54

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)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-28T20:58:50', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '255e8603-ca93-489d-8988-9cf12ae7e5ca'	System	29 Sep 2020 02:00:16
User entered '6'	System	29 Sep 2020 02:00:16

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:54

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-28T20:59:50', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '255e8603-ca93-489d-8988-9cf12ae7e5ca'	System	29 Sep 2020 02:00:16
User entered 'No (N)'	System	29 Sep 2020 02:00:16

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:54

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-28T20:59:57', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '255e8603-ca93-489d-8988-9cf12ae7e5ca'	System	29 Sep 2020 02:00:16
User entered 'None (1)'	System	29 Sep 2020 02:00:16

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-28T21:00:14', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '255e8603-ca93-489d-8988-9cf12ae7e5ca'	System	29 Sep 2020 02:00:16
User entered '28 Sep 2020 21:00'	System	29 Sep 2020 02:00:16

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 4'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:54

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-29T22:31:55', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '72e4a4ac-3ccd-4647-8958-7f86165ea30e'	System	30 Sep 2020 03:32:13
User entered 'Does not interfere with activity (2)'	System	30 Sep 2020 03:32:13

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-29T22:31:57', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '72e4a4ac-3ccd-4647-8958-7f86165ea30e'	System	30 Sep 2020 03:32:13
User entered 'No (N)'	System	30 Sep 2020 03:32:13

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:54

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-29T22:32:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '72e4a4ac-3ccd-4647-8958-7f86165ea30e'	System	30 Sep 2020 03:32:13
User entered 'No (N)'	System	30 Sep 2020 03:32:13

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:54

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-29T22:32:02', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '72e4a4ac-3ccd-4647-8958-7f86165ea30e'	System	30 Sep 2020 03:32:13
User entered 'None (1)'	System	30 Sep 2020 03:32:13

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-29T22:32:07', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '72e4a4ac-3ccd-4647-8958-7f86165ea30e'	System	30 Sep 2020 03:32:13
User entered '29 Sep 2020 22:32'	System	30 Sep 2020 03:32:13

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '29 Sep 2020 12:00'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '30 Sep 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 5'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:54

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-30T22:20:05', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '727b4fea-0dc4-403d-85d6-4fd487498cb9'	System	01 Oct 2020 03:20:22
User entered 'None (1)'	System	01 Oct 2020 03:20:22

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-30T22:20:08', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '727b4fea-0dc4-403d-85d6-4fd487498cb9'	System	01 Oct 2020 03:20:22
User entered 'No (N)'	System	01 Oct 2020 03:20:22

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:54

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-30T22:20:13', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '727b4fea-0dc4-403d-85d6-4fd487498cb9'	System	01 Oct 2020 03:20:22
User entered 'No (N)'	System	01 Oct 2020 03:20:22

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:54

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-30T22:20:16', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '727b4fea-0dc4-403d-85d6-4fd487498cb9'	System	01 Oct 2020 03:20:22
User entered 'None (1)'	System	01 Oct 2020 03:20:22

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-30T22:20:19', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '727b4fea-0dc4-403d-85d6-4fd487498cb9'	System	01 Oct 2020 03:20:22
User entered '30 Sep 2020 22:20'	System	01 Oct 2020 03:20:22

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '30 Sep 2020 12:00'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '01 Oct 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 6'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:54

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-01T20:37:52', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '1d37fc7e-15ca-49a2-91d0-59937076df1a'	System	02 Oct 2020 01:38:07
User entered 'None (1)'	System	02 Oct 2020 01:38:07

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-01T20:37:55', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '1d37fc7e-15ca-49a2-91d0-59937076df1a'	System	02 Oct 2020 01:38:07
User entered 'No (N)'	System	02 Oct 2020 01:38:07

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:54

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-01T20:37:57', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '1d37fc7e-15ca-49a2-91d0-59937076df1a'	System	02 Oct 2020 01:38:07
User entered 'No (N)'	System	02 Oct 2020 01:38:07

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:54

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-01T20:38:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '1d37fc7e-15ca-49a2-91d0-59937076df1a'	System	02 Oct 2020 01:38:07
User entered 'None (1)'	System	02 Oct 2020 01:38:07

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-01T20:38:04', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '1d37fc7e-15ca-49a2-91d0-59937076df1a'	System	02 Oct 2020 01:38:07
User entered '01 Oct 2020 20:38'	System	02 Oct 2020 01:38:07

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '01 Oct 2020 12:00'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '02 Oct 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 7'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:54

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-02T23:27:11', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '61d1b0d9-327a-49de-b400-b07c713178d5'	System	03 Oct 2020 04:27:28
User entered 'None (1)'	System	03 Oct 2020 04:27:28

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-02T23:27:13', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '61d1b0d9-327a-49de-b400-b07c713178d5'	System	03 Oct 2020 04:27:28
User entered 'No (N)'	System	03 Oct 2020 04:27:28

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:54

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-02T23:27:16', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '61d1b0d9-327a-49de-b400-b07c713178d5'	System	03 Oct 2020 04:27:28
User entered 'No (N)'	System	03 Oct 2020 04:27:28

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:54

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-02T23:27:19', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '61d1b0d9-327a-49de-b400-b07c713178d5'	System	03 Oct 2020 04:27:28
User entered 'None (1)'	System	03 Oct 2020 04:27:28

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-02T23:27:26', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '61d1b0d9-327a-49de-b400-b07c713178d5'	System	03 Oct 2020 04:27:28
User entered '02 Oct 2020 23:27'	System	03 Oct 2020 04:27:28

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '02 Oct 2020 12:00'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '03 Oct 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T10:19:24', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '0b989698-7fba-41e6-88d8-011a1c52dcb8'	System	26 Sep 2020 15:19:45
User entered 'None (0)'	System	26 Sep 2020 15:19:45

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T10:19:26', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '0b989698-7fba-41e6-88d8-011a1c52dcb8'	System	26 Sep 2020 15:19:45
User entered 'None (0)'	System	26 Sep 2020 15:19:45

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T10:19:27', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '0b989698-7fba-41e6-88d8-011a1c52dcb8'	System	26 Sep 2020 15:19:45
User entered 'None (0)'	System	26 Sep 2020 15:19:45

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T10:19:29', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '0b989698-7fba-41e6-88d8-011a1c52dcb8'	System	26 Sep 2020 15:19:45
User entered 'None (0)'	System	26 Sep 2020 15:19:45

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T10:19:31', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '0b989698-7fba-41e6-88d8-011a1c52dcb8'	System	26 Sep 2020 15:19:45
User entered 'None (0)'	System	26 Sep 2020 15:19:45

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T10:19:32', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '0b989698-7fba-41e6-88d8-011a1c52dcb8'	System	26 Sep 2020 15:19:45
User entered 'None (0)'	System	26 Sep 2020 15:19:45

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

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)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T10:19:36', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '0b989698-7fba-41e6-88d8-011a1c52dcb8'	System	26 Sep 2020 15:19:45
User entered 'No (N)'	System	26 Sep 2020 15:19:45

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T10:19:40', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '0b989698-7fba-41e6-88d8-011a1c52dcb8'	System	26 Sep 2020 15:19:45
User entered '26 Sep 2020 10:19'	System	26 Sep 2020 15:19:45

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '26 Sep 2020 10:02'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '26 Sep 2020 12:32'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 1, after vaccination (at home)'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T21:33:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f1f8296e-b326-476d-b3e7-4a73b1a640d8'	System	27 Sep 2020 02:33:24
User entered 'None (0)'	System	27 Sep 2020 02:33:24

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T21:33:02', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f1f8296e-b326-476d-b3e7-4a73b1a640d8'	System	27 Sep 2020 02:33:24
User entered 'None (0)'	System	27 Sep 2020 02:33:24

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T21:33:04', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f1f8296e-b326-476d-b3e7-4a73b1a640d8'	System	27 Sep 2020 02:33:24
User entered 'None (0)'	System	27 Sep 2020 02:33:24

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T21:33:06', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f1f8296e-b326-476d-b3e7-4a73b1a640d8'	System	27 Sep 2020 02:33:24
User entered 'None (0)'	System	27 Sep 2020 02:33:24

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T21:33:08', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f1f8296e-b326-476d-b3e7-4a73b1a640d8'	System	27 Sep 2020 02:33:24
User entered 'None (0)'	System	27 Sep 2020 02:33:24

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T21:33:10', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f1f8296e-b326-476d-b3e7-4a73b1a640d8'	System	27 Sep 2020 02:33:24
User entered 'None (0)'	System	27 Sep 2020 02:33:24

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

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)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T21:33:14', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f1f8296e-b326-476d-b3e7-4a73b1a640d8'	System	27 Sep 2020 02:33:24
User entered 'No (N)'	System	27 Sep 2020 02:33:24

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T21:33:18', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f1f8296e-b326-476d-b3e7-4a73b1a640d8'	System	27 Sep 2020 02:33:24
User entered '26 Sep 2020 21:33'	System	27 Sep 2020 02:33:24

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '26 Sep 2020 13:27'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '27 Sep 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 2'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-27T21:06:25', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '6589c7bb-d701-49f9-ab8e-05482bea70b5'	System	28 Sep 2020 02:07:49
User entered 'No interference with activity (1)'	System	28 Sep 2020 02:07:49

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-27T21:06:38', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '6589c7bb-d701-49f9-ab8e-05482bea70b5'	System	28 Sep 2020 02:07:49
User entered 'Some interference with activity (2)'	System	28 Sep 2020 02:07:49

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-27T21:06:45', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '6589c7bb-d701-49f9-ab8e-05482bea70b5'	System	28 Sep 2020 02:07:49
User entered 'Some interference with activity (2)'	System	28 Sep 2020 02:07:49

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-27T21:06:50', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '6589c7bb-d701-49f9-ab8e-05482bea70b5'	System	28 Sep 2020 02:07:49
User entered 'None (0)'	System	28 Sep 2020 02:07:49

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-27T21:07:20', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '6589c7bb-d701-49f9-ab8e-05482bea70b5'	System	28 Sep 2020 02:07:49
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	28 Sep 2020 02:07:49

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-27T21:07:23', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '6589c7bb-d701-49f9-ab8e-05482bea70b5'	System	28 Sep 2020 02:07:49
User entered 'None (0)'	System	28 Sep 2020 02:07:49

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:54

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)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-27T21:07:28', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '6589c7bb-d701-49f9-ab8e-05482bea70b5'	System	28 Sep 2020 02:07:49
User entered 'No (N)'	System	28 Sep 2020 02:07:49

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-27T21:07:43', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '6589c7bb-d701-49f9-ab8e-05482bea70b5'	System	28 Sep 2020 02:07:49
User entered '27 Sep 2020 21:07'	System	28 Sep 2020 02:07:49

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 3'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-28T21:00:20', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '8575d4f6-e2b2-4106-b841-ea02d034dc5d'	System	29 Sep 2020 02:00:45
User entered 'None (0)'	System	29 Sep 2020 02:00:45

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-28T21:00:25', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '8575d4f6-e2b2-4106-b841-ea02d034dc5d'	System	29 Sep 2020 02:00:45
User entered 'No interference with activity (1)'	System	29 Sep 2020 02:00:45

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-28T21:00:27', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '8575d4f6-e2b2-4106-b841-ea02d034dc5d'	System	29 Sep 2020 02:00:45
User entered 'None (0)'	System	29 Sep 2020 02:00:45

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-28T21:00:29', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '8575d4f6-e2b2-4106-b841-ea02d034dc5d'	System	29 Sep 2020 02:00:45
User entered 'None (0)'	System	29 Sep 2020 02:00:45

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-28T21:00:31', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '8575d4f6-e2b2-4106-b841-ea02d034dc5d'	System	29 Sep 2020 02:00:45
User entered 'None (0)'	System	29 Sep 2020 02:00:45

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-28T21:00:33', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '8575d4f6-e2b2-4106-b841-ea02d034dc5d'	System	29 Sep 2020 02:00:45
User entered 'None (0)'	System	29 Sep 2020 02:00:45

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:54

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)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-28T21:00:37', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '8575d4f6-e2b2-4106-b841-ea02d034dc5d'	System	29 Sep 2020 02:00:45
User entered 'No (N)'	System	29 Sep 2020 02:00:45

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-28T21:00:43', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '8575d4f6-e2b2-4106-b841-ea02d034dc5d'	System	29 Sep 2020 02:00:45
User entered '28 Sep 2020 21:00'	System	29 Sep 2020 02:00:45

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 4'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-29T22:32:11', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '7b335c6c-e451-4bf1-940d-676ccb4fded2'	System	30 Sep 2020 03:32:27
User entered 'None (0)'	System	30 Sep 2020 03:32:27

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-29T22:32:13', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '7b335c6c-e451-4bf1-940d-676ccb4fded2'	System	30 Sep 2020 03:32:27
User entered 'None (0)'	System	30 Sep 2020 03:32:27

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-29T22:32:15', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '7b335c6c-e451-4bf1-940d-676ccb4fded2'	System	30 Sep 2020 03:32:27
User entered 'None (0)'	System	30 Sep 2020 03:32:27

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-29T22:32:17', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '7b335c6c-e451-4bf1-940d-676ccb4fded2'	System	30 Sep 2020 03:32:27
User entered 'None (0)'	System	30 Sep 2020 03:32:27

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-29T22:32:19', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '7b335c6c-e451-4bf1-940d-676ccb4fded2'	System	30 Sep 2020 03:32:27
User entered 'None (0)'	System	30 Sep 2020 03:32:27

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-29T22:32:20', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '7b335c6c-e451-4bf1-940d-676ccb4fded2'	System	30 Sep 2020 03:32:27
User entered 'None (0)'	System	30 Sep 2020 03:32:27

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:54

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)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-29T22:32:22', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '7b335c6c-e451-4bf1-940d-676ccb4fded2'	System	30 Sep 2020 03:32:27
User entered 'No (N)'	System	30 Sep 2020 03:32:27

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-29T22:32:25', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '7b335c6c-e451-4bf1-940d-676ccb4fded2'	System	30 Sep 2020 03:32:27
User entered '29 Sep 2020 22:32'	System	30 Sep 2020 03:32:27

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '29 Sep 2020 12:00'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '30 Sep 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 5'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-30T22:19:46', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'd1820b2f-8a7b-4b0b-bd2a-d672326a4e4e'	System	01 Oct 2020 03:20:05
User entered 'None (0)'	System	01 Oct 2020 03:20:05

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-30T22:19:48', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'd1820b2f-8a7b-4b0b-bd2a-d672326a4e4e'	System	01 Oct 2020 03:20:05
User entered 'None (0)'	System	01 Oct 2020 03:20:05

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-30T22:19:50', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'd1820b2f-8a7b-4b0b-bd2a-d672326a4e4e'	System	01 Oct 2020 03:20:05
User entered 'None (0)'	System	01 Oct 2020 03:20:05

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-30T22:19:52', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'd1820b2f-8a7b-4b0b-bd2a-d672326a4e4e'	System	01 Oct 2020 03:20:05
User entered 'None (0)'	System	01 Oct 2020 03:20:05

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-30T22:19:53', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'd1820b2f-8a7b-4b0b-bd2a-d672326a4e4e'	System	01 Oct 2020 03:20:05
User entered 'None (0)'	System	01 Oct 2020 03:20:05

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-30T22:19:55', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'd1820b2f-8a7b-4b0b-bd2a-d672326a4e4e'	System	01 Oct 2020 03:20:05
User entered 'None (0)'	System	01 Oct 2020 03:20:05

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:54

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)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-30T22:19:57', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'd1820b2f-8a7b-4b0b-bd2a-d672326a4e4'	System	01 Oct 2020 03:20:05
User entered 'No (N)'	System	01 Oct 2020 03:20:05

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-30T22:20:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'd1820b2f-8a7b-4b0b-bd2a-d672326a4e4e'	System	01 Oct 2020 03:20:05
User entered '30 Sep 2020 22:20'	System	01 Oct 2020 03:20:05

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '30 Sep 2020 12:00'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '01 Oct 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 6'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-01T20:38:09', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '2dcb4ff1-8f3f-4b8b-aa4d-d9d5ab206754'	System	02 Oct 2020 01:38:36
User entered 'None (0)'	System	02 Oct 2020 01:38:36

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-01T20:38:12', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '2dcb4ff1-8f3f-4b8b-aa4d-d9d5ab206754'	System	02 Oct 2020 01:38:36
User entered 'None (0)'	System	02 Oct 2020 01:38:36

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-01T20:38:14', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '2dcb4ff1-8f3f-4b8b-aa4d-d9d5ab206754'	System	02 Oct 2020 01:38:36
User entered 'None (0)'	System	02 Oct 2020 01:38:36

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-01T20:38:17', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '2dcb4ff1-8f3f-4b8b-aa4d-d9d5ab206754'	System	02 Oct 2020 01:38:36
User entered 'None (0)'	System	02 Oct 2020 01:38:36

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-01T20:38:19', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '2dcb4ff1-8f3f-4b8b-aa4d-d9d5ab206754'	System	02 Oct 2020 01:38:36
User entered 'None (0)'	System	02 Oct 2020 01:38:36

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-01T20:38:21', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '2dcb4ff1-8f3f-4b8b-aa4d-d9d5ab206754'	System	02 Oct 2020 01:38:36
User entered 'None (0)'	System	02 Oct 2020 01:38:36

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:54

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)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-01T20:38:26', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '2dcb4ff1-8f3f-4b8b-aa4d-d9d5ab206754'	System	02 Oct 2020 01:38:36
User entered 'No (N)'	System	02 Oct 2020 01:38:36

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-01T20:38:33', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '2dcb4ff1-8f3f-4b8b-aa4d-d9d5ab206754'	System	02 Oct 2020 01:38:36
User entered '01 Oct 2020 20:38'	System	02 Oct 2020 01:38:36

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '01 Oct 2020 12:00'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '02 Oct 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 7'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-02T23:27:30', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '45274eb2-df34-4e0e-a4c6-dac429de6f9a'	System	03 Oct 2020 04:27:51
User entered 'None (0)'	System	03 Oct 2020 04:27:51

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-02T23:27:32', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '45274eb2-df34-4e0e-a4c6-dac429de6f9a'	System	03 Oct 2020 04:27:51
User entered 'None (0)'	System	03 Oct 2020 04:27:51

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-02T23:27:34', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '45274eb2-df34-4e0e-a4c6-dac429de6f9a'	System	03 Oct 2020 04:27:51
User entered 'None (0)'	System	03 Oct 2020 04:27:51

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-02T23:27:36', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '45274eb2-df34-4e0e-a4c6-dac429de6f9a'	System	03 Oct 2020 04:27:51
User entered 'None (0)'	System	03 Oct 2020 04:27:51

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-02T23:27:38', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '45274eb2-df34-4e0e-a4c6-dac429de6f9a'	System	03 Oct 2020 04:27:51
User entered 'None (0)'	System	03 Oct 2020 04:27:51

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-02T23:27:40', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '45274eb2-df34-4e0e-a4c6-dac429de6f9a'	System	03 Oct 2020 04:27:51
User entered 'None (0)'	System	03 Oct 2020 04:27:51

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:54

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)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-02T23:27:43', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '45274eb2-df34-4e0e-a4c6-dac429de6f9a'	System	03 Oct 2020 04:27:51
User entered 'No (N)'	System	03 Oct 2020 04:27:51

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-02T23:27:50', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '45274eb2-df34-4e0e-a4c6-dac429de6f9a'	System	03 Oct 2020 04:27:51
User entered '02 Oct 2020 23:27'	System	03 Oct 2020 04:27:51

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '02 Oct 2020 12:00'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
User entered '03 Oct 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	04 Oct 2020 20:03:31

US3292365

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '4 Oct 2020'	(b) (4) Kristy Trevino (b) (4)	04 Oct 2020 20:03:31

US3292365

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kristy Trevino (b) (4)	04 Oct 2020 20:03:31

US3292365

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4) Kristy Trevino (b) (4)	04 Oct 2020 20:03:31

US3292365

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	04 Oct 2020 20:03:35

US3292365

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered 'l'	System	04 Oct 2020 20:03:35

US3292365

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Oct 2020 15:36:40

US3292365

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '10 Oct 2020'	(b) (4), (b) (6)	10 Oct 2020 15:36:40

US3292365

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	10 Oct 2020 15:36:40

US3292365

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4), (b) (6)	10 Oct 2020 15:36:40

US3292365

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Oct 2020 15:36:46

US3292365

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered 'l'	System	10 Oct 2020 15:36:46

US3292365

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	17 Oct 2020 15:31:31

US3292365

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '17 Oct 2020'	(b) (4) Kristy Trevino (b) (4)	17 Oct 2020 15:31:31

US3292365

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kristy Trevino (b) (4)	17 Oct 2020 15:31:31

US3292365

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4) Kristy Trevino (b) (4) (b) (4)	17 Oct 2020 15:31:31

US3292365

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	17 Oct 2020 15:31:42

US3292365

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered 'l'	System	17 Oct 2020 15:31:42

US3292365

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 14:05:29

US3292365

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:54

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '27 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 14:05:29

US3292365

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:54

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	27 Oct 2020 14:05:29

US3292365

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered 'VISIT3'	System	27 Oct 2020 14:05:29

US3292365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 14:06:18

US3292365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '27 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 14:06:18

US3292365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '07:54'	(b) (4), (b) (6)	27 Oct 2020 14:06:18

US3292365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered '27 Oct 2020 07:54'	System	27 Oct 2020 14:06:18

US3292365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '36.6' C	(b) (4), (b) (6)	27 Oct 2020 14:06:18

US3292365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Oral (Oral)'	(b) (4), (b) (6)	27 Oct 2020 14:06:18

US3292365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 14:06:18

US3292365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '54'	(b) (4), (b) (6)	27 Oct 2020 14:06:18

US3292365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered 'bpm'	System	27 Oct 2020 14:06:18

US3292365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '16'	(b) (4), (b) (6)	27 Oct 2020 14:06:18

US3292365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered 'breaths/min'	System	27 Oct 2020 14:06:18

US3292365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '126'	(b) (4), (b) (6)	27 Oct 2020 14:06:18

US3292365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered 'mmHg'	System	27 Oct 2020 14:06:18

US3292365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '88'	(b) (4), (b) (6)	27 Oct 2020 14:06:18

US3292365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered 'mmHg'	System	27 Oct 2020 14:06:18

US3292365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18

US3292365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18

US3292365

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:27:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 14:06:23

US3292365

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:27:54

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 14:06:23

US3292365

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 14:06:56

US3292365

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:54

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '27 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 14:06:56

US3292365

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:54

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '08:07'	(b) (4), (b) (6)	27 Oct 2020 14:06:56

US3292365

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered '27 Oct 2020 08:07'	System	27 Oct 2020 14:06:56

US3292365

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 14:07:01

US3292365

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered 'I'	System	27 Oct 2020 14:07:01

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 64'	System	29 Aug 2020 18:21:38

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[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)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-31T13:54:30', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'a5fc3085-a248-4069-b43e-1216bd360f81'	System	31 Oct 2020 18:54:47
User entered 'No (N)'	System	31 Oct 2020 18:54:47

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

Have you been exposed to someone with 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)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-31T13:54:35', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'a5fc3085-a248-4069-b43e-1216bd360f81'	System	31 Oct 2020 18:54:47
User entered 'No (N)'	System	31 Oct 2020 18:54:47

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-31T13:54:44', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'a5fc3085-a248-4069-b43e-1216bd360f81'	System	31 Oct 2020 18:54:47
User entered '31 Oct 2020 13:54:44'	System	31 Oct 2020 18:54:47

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	29 Aug 2020 18:21:38
User entered '29 Oct 2020 00:01'	System	29 Aug 2020 18:21:38

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	29 Aug 2020 18:21:38
User entered '02 Nov 2020 23:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 71'	System	29 Aug 2020 18:21:38

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[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)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-11-07T16:46:24', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '09067362-821f-44d5-8842-67e0f7fa6c72'	System	07 Nov 2020 22:46:42
User entered 'No (N)'	System	07 Nov 2020 22:46:42

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

Have you been exposed to someone with 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)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-11-07T16:46:34', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '09067362-821f-44d5-8842-67e0f7fa6c72'	System	07 Nov 2020 22:46:42
User entered 'No (N)'	System	07 Nov 2020 22:46:42

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-11-07T16:46:40', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '09067362-821f-44d5-8842-67e0f7fa6c72'	System	07 Nov 2020 22:46:42
User entered '07 Nov 2020 16:46:40'	System	07 Nov 2020 22:46:42

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	29 Aug 2020 18:21:38
User entered '05 Nov 2020 00:01'	System	29 Aug 2020 18:21:38

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	29 Aug 2020 18:21:38
User entered '09 Nov 2020 23:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 78'	System	29 Aug 2020 18:21:38

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[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)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-11-14T12:55:10', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'a3f87f2c-8ecd-47f7-8b3c-58ec30b5a589'	System	14 Nov 2020 18:56:20
User entered 'Yes (Y)'	System	14 Nov 2020 18:56:20

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

Have you been exposed to someone with 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)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-11-14T12:55:16', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'a3f87f2c-8ecd-47f7-8b3c-58ec30b5a589'	System	14 Nov 2020 18:56:20
User entered 'No (N)'	System	14 Nov 2020 18:56:20

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-11-14T12:55:22', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'a3f87f2c-8ecd-47f7-8b3c-58ec30b5a589'	System	14 Nov 2020 18:56:20
User entered 'No (N)'	System	14 Nov 2020 18:56:20

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-11-14T12:55:32', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'a3f87f2c-8ecd-47f7-8b3c-58ec30b5a589'	System	14 Nov 2020 18:56:20
User entered 'Yes (Y)'	System	14 Nov 2020 18:56:20

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-11-14T12:55:48', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'a3f87f2c-8ecd-47f7-8b3c-58ec30b5a589'	System	14 Nov 2020 18:56:20
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Nov 2020 18:56:20

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-11-14T12:56:08', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'a3f87f2c-8ecd-47f7-8b3c-58ec30b5a589'	System	14 Nov 2020 18:56:20
User entered '14 Nov 2020 12:56:08'	System	14 Nov 2020 18:56:20

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	29 Aug 2020 18:21:38
User entered '12 Nov 2020 00:01'	System	29 Aug 2020 18:21:38

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:20:53
Data entry locked.	System	29 Aug 2020 18:21:38
User entered '16 Nov 2020 23:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-11-20T19:06:50', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f0aa5784-3679-4ce2-b561-5be4fa2e9c83'	System	21 Nov 2020 01:07:09
User entered 'No (N)'	System	21 Nov 2020 01:07:09

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-11-20T19:06:56', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f0aa5784-3679-4ce2-b561-5be4fa2e9c83'	System	21 Nov 2020 01:07:09
User entered 'No (N)'	System	21 Nov 2020 01:07:09

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-11-20T19:07:04', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f0aa5784-3679-4ce2-b561-5be4fa2e9c83'	System	21 Nov 2020 01:07:09
User entered '20 Nov 2020 19:07:04'	System	21 Nov 2020 01:07:09

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '16 Nov 2020 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '20 Nov 2020 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-11-25T12:00:42', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '9c54199c-bfbb-4962-b4d2-60654c10dc76'	System	25 Nov 2020 18:00:52
User entered 'No (N)'	System	25 Nov 2020 18:00:52

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-11-25T12:00:46', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '9c54199c-bfbb-4962-b4d2-60654c10dc76'	System	25 Nov 2020 18:00:52
User entered 'No (N)'	System	25 Nov 2020 18:00:52

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-11-25T12:00:50', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '9c54199c-bfbb-4962-b4d2-60654c10dc76'	System	25 Nov 2020 18:00:52
User entered '25 Nov 2020 12:00:50'	System	25 Nov 2020 18:00:52

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '23 Nov 2020 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '27 Nov 2020 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-12-03T15:56:28', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'cbe22c89-6f36-4276-ba74-50e0d6275aa7'	System	03 Dec 2020 21:56:43
User entered 'No (N)'	System	03 Dec 2020 21:56:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-12-03T15:56:31', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'cbe22c89-6f36-4276-ba74-50e0d6275aa7'	System	03 Dec 2020 21:56:43
User entered 'No (N)'	System	03 Dec 2020 21:56:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-12-03T15:56:37', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'cbe22c89-6f36-4276-ba74-50e0d6275aa7'	System	03 Dec 2020 21:56:43
User entered '03 Dec 2020 15:56:37'	System	03 Dec 2020 21:56:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '30 Nov 2020 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '04 Dec 2020 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-12-10T13:54:02', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '2f351d14-e5af-4a9c-84fd-5a61baf9713'	System	10 Dec 2020 19:54:19
User entered 'No (N)'	System	10 Dec 2020 19:54:19

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-12-10T13:54:08', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '2f351d14-e5af-4a9c-84fd-5a61baf9713'	System	10 Dec 2020 19:54:19
User entered 'No (N)'	System	10 Dec 2020 19:54:19

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-12-10T13:54:16', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '2f351d14-e5af-4a9c-84fd-5a61baf9713'	System	10 Dec 2020 19:54:19
User entered '10 Dec 2020 13:54:16'	System	10 Dec 2020 19:54:19

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '07 Dec 2020 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '11 Dec 2020 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-12-17T18:01:50', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'da49b427-2153-4d81-9e64-efbf463d67c9'	System	18 Dec 2020 00:02:22
User entered 'No (N)'	System	18 Dec 2020 00:02:22

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-12-17T18:02:16', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'da49b427-2153-4d81-9e64-efbf463d67c9'	System	18 Dec 2020 00:02:22
User entered 'No (N)'	System	18 Dec 2020 00:02:22

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-12-17T18:02:20', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'da49b427-2153-4d81-9e64-efbf463d67c9'	System	18 Dec 2020 00:02:22
User entered '17 Dec 2020 18:02:20'	System	18 Dec 2020 00:02:22

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '14 Dec 2020 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '18 Dec 2020 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-12-23T12:00:56', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '830884fc-2584-436c-9673-f01e84243f87'	System	23 Dec 2020 18:01:11
User entered 'No (N)'	System	23 Dec 2020 18:01:11

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-12-23T12:01:02', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '830884fc-2584-436c-9673-f01e84243f87'	System	23 Dec 2020 18:01:11
User entered 'No (N)'	System	23 Dec 2020 18:01:11

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-12-23T12:01:06', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '830884fc-2584-436c-9673-f01e84243f87'	System	23 Dec 2020 18:01:11
User entered '23 Dec 2020 12:01:06'	System	23 Dec 2020 18:01:11

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '21 Dec 2020 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '25 Dec 2020 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-12-30T16:56:53', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '654b23d5-e433-49b0-9a69-3a4ad0bc0a67'	System	30 Dec 2020 22:57:08
User entered 'No (N)'	System	30 Dec 2020 22:57:08

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-12-30T16:57:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '654b23d5-e433-49b0-9a69-3a4ad0bc0a67'	System	30 Dec 2020 22:57:08
User entered 'No (N)'	System	30 Dec 2020 22:57:08

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-12-30T16:57:05', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '654b23d5-e433-49b0-9a69-3a4ad0bc0a67'	System	30 Dec 2020 22:57:08
User entered '30 Dec 2020 16:57:05'	System	30 Dec 2020 22:57:08

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '28 Dec 2020 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '01 Jan 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-01-06T10:00:51', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '3169133d-b6a5-4a20-9bde-823471e022e4'	System	06 Jan 2021 16:01:10
User entered 'No (N)'	System	06 Jan 2021 16:01:10

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-01-06T10:01:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '3169133d-b6a5-4a20-9bde-823471e022e4'	System	06 Jan 2021 16:01:10
User entered 'No (N)'	System	06 Jan 2021 16:01:10

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-01-06T10:01:04', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '3169133d-b6a5-4a20-9bde-823471e022e4'	System	06 Jan 2021 16:01:10
User entered '06 Jan 2021 10:01:04'	System	06 Jan 2021 16:01:10

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '04 Jan 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '08 Jan 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-01-13T07:19:42', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'c18599af-d38b-4785-8c63-dfacd2187418'	System	13 Jan 2021 13:20:02
User entered 'No (N)'	System	13 Jan 2021 13:20:02

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-01-13T07:19:48', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'c18599af-d38b-4785-8c63-dfacd2187418'	System	13 Jan 2021 13:20:02
User entered 'No (N)'	System	13 Jan 2021 13:20:02

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-01-13T07:19:56', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'c18599af-d38b-4785-8c63-dfacd2187418' User entered '13 Jan 2021 07:19:56'	System	13 Jan 2021 13:20:02

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '11 Jan 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '15 Jan 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-01-20T15:41:40', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'c79e935d-ecef-4e41-85ac-42c8ddd6fb54'	System	20 Jan 2021 21:41:53
User entered 'No (N)'	System	20 Jan 2021 21:41:53

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-01-20T15:41:46', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'c79e935d-ecef-4e41-85ac-42c8ddd6fb54'	System	20 Jan 2021 21:41:53
User entered 'No (N)'	System	20 Jan 2021 21:41:53

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-01-20T15:41:50', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'c79e935d-ecef-4e41-85ac-42c8ddd6fb54'	System	20 Jan 2021 21:41:53
User entered '20 Jan 2021 15:41:50'	System	20 Jan 2021 21:41:53

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '18 Jan 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '22 Jan 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-01-27T10:40:56', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '65db6d3f-706d-4b7c-b427-21a9354cc761'	System	27 Jan 2021 16:41:10
User entered 'No (N)'	System	27 Jan 2021 16:41:10

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-01-27T10:41:02', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '65db6d3f-706d-4b7c-b427-21a9354cc761'	System	27 Jan 2021 16:41:10
User entered 'No (N)'	System	27 Jan 2021 16:41:10

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-01-27T10:41:06', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '65db6d3f-706d-4b7c-b427-21a9354cc761' User entered '27 Jan 2021 10:41:06'	System	27 Jan 2021 16:41:10

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '25 Jan 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '29 Jan 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-02-03T12:04:54', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'be820872-2b2e-4c29-9686-870cc210a2e9'	System	03 Feb 2021 18:07:39
User entered 'No (N)'	System	03 Feb 2021 18:07:39

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-02-03T12:05:07', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'be820872-2b2e-4c29-9686-870cc210a2e9'	System	03 Feb 2021 18:07:39
User entered 'No (N)'	System	03 Feb 2021 18:07:39

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-02-03T12:05:16', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'be820872-2b2e-4c29-9686-870cc210a2e9'	System	03 Feb 2021 18:07:39
User entered '03 Feb 2021 12:05:16'	System	03 Feb 2021 18:07:39

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '01 Feb 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '05 Feb 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-02-10T12:02:02', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'a09280f1-a780-4a8d-9f7a-ce468e8ae080'	System	10 Feb 2021 18:04:53
User entered 'No (N)'	System	10 Feb 2021 18:04:53

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-02-10T12:02:04', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'a09280f1-a780-4a8d-9f7a-ce468e8ae080'	System	10 Feb 2021 18:04:53
User entered 'No (N)'	System	10 Feb 2021 18:04:53

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-02-10T12:02:11', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'a09280f1-a780-4a8d-9f7a-ce468e8ae080'	System	10 Feb 2021 18:04:53
User entered '10 Feb 2021 12:02:11'	System	10 Feb 2021 18:04:53

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '08 Feb 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '12 Feb 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-02-19T09:09:35', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'c9ba0cf2-ee41-4c63-8ec8-5ae7ae89bef6'	System	19 Feb 2021 15:09:43
User entered 'No (N)'	System	19 Feb 2021 15:09:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-02-19T09:09:37', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'c9ba0cf2-ee41-4c63-8ec8-5ae7ae89bef6'	System	19 Feb 2021 15:09:43
User entered 'No (N)'	System	19 Feb 2021 15:09:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-02-19T09:09:40', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'c9ba0cf2-ee41-4c63-8ec8-5ae7ae89bef6' User entered '19 Feb 2021 09:09:40'	System	19 Feb 2021 15:09:43
	System	19 Feb 2021 15:09:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '15 Feb 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '19 Feb 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-02-23T08:55:20-06:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'fb837815-da7d-4ba2-bd07-9fbb094b24b4'	System	23 Feb 2021 14:57:21
User entered 'Yes (Y)'	System	23 Feb 2021 14:57:21

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-02-23T08:55:25-06:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'fb837815-da7d-4ba2-bd07-9fbb094b24b4'	System	23 Feb 2021 14:57:21
User entered 'No (N)'	System	23 Feb 2021 14:57:21

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-02-23T08:55:30-06:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'fb837815-da7d-4ba2-bd07-9fbb094b24b4' User entered 'No (N)'	System	23 Feb 2021 14:57:21
	System	23 Feb 2021 14:57:21

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-02-23T08:55:38-06:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'fb837815-da7d-4ba2-bd07-9fbb094b24b4' User entered 'No (N)'	System	23 Feb 2021 14:57:21
	System	23 Feb 2021 14:57:21

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-02-23T08:57:20-06:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'fb837815-da7d-4ba2-bd07-9fbb094b24b4' User entered '23 Feb 2021 08:57:20'	System	23 Feb 2021 14:57:21
	System	23 Feb 2021 14:57:21

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '22 Feb 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '26 Feb 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-03-03T12:01:31-06:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '4d4f269d-be34-47e7-9057-6ec3b6038192'	System	03 Mar 2021 18:04:30
User entered 'No (N)'	System	03 Mar 2021 18:04:30

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-03-03T12:01:35-06:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '4d4f269d-be34-47e7-9057-6ec3b6038192'	System	03 Mar 2021 18:04:30
User entered 'No (N)'	System	03 Mar 2021 18:04:30

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-03-03T12:01:55-06:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '4d4f269d-be34-47e7-9057-6ec3b6038192'	System	03 Mar 2021 18:04:30
User entered '03 Mar 2021 12:01:55'	System	03 Mar 2021 18:04:30

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '01 Mar 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '05 Mar 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-03-10T12:09:10-06:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'cf493c93-1f30-4016-bf80-e556e3fb951c'	System	10 Mar 2021 18:12:41
User entered 'No (N)'	System	10 Mar 2021 18:12:41

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-03-10T12:09:13-06:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'cf493c93-1f30-4016-bf80-e556e3fb951c'	System	10 Mar 2021 18:12:41
User entered 'No (N)'	System	10 Mar 2021 18:12:41

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-03-10T12:09:24-06:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'cf493c93-1f30-4016-bf80-e556e3fb951c' User entered '10 Mar 2021 12:09:24'	System	10 Mar 2021 18:12:41
	System	10 Mar 2021 18:12:41

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '08 Mar 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '12 Mar 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-03-18T11:56:27-05:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '0c58b1a8-1026-4826-861b-7d69da0fb900'	System	18 Mar 2021 16:56:45
User entered 'No (N)'	System	18 Mar 2021 16:56:45

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-03-18T11:56:35-05:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '0c58b1a8-1026-4826-861b-7d69da0fb900'	System	18 Mar 2021 16:56:45
User entered 'No (N)'	System	18 Mar 2021 16:56:45

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-03-18T11:56:40-05:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '0c58b1a8-1026-4826-861b-7d69da0fb900'	System	18 Mar 2021 16:56:45
User entered '18 Mar 2021 11:56:40'	System	18 Mar 2021 16:56:45

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '15 Mar 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '19 Mar 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '22 Mar 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '26 Mar 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-04-01T10:53:18-05:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'e686919f-587e-4504-b450-8cd075c78f45'	System	01 Apr 2021 15:53:31
User entered 'No (N)'	System	01 Apr 2021 15:53:31

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-04-01T10:53:22-05:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'e686919f-587e-4504-b450-8cd075c78f45'	System	01 Apr 2021 15:53:31
User entered 'No (N)'	System	01 Apr 2021 15:53:31

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-04-01T10:53:26-05:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'e686919f-587e-4504-b450-8cd075c78f45'	System	01 Apr 2021 15:53:31
User entered '01 Apr 2021 10:53:26'	System	01 Apr 2021 15:53:31

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '29 Mar 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '02 Apr 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-04-08T12:00:21-05:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'a57212cc-6704-4bc8-9853-17a2e6cad72a' User entered 'No (N)'	System	08 Apr 2021 17:00:42

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-04-08T12:00:23-05:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'a57212cc-6704-4bc8-9853-17a2e6cad72a' User entered 'No (N)'	System	08 Apr 2021 17:00:42
	System	08 Apr 2021 17:00:42

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-04-08T12:00:28-05:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'a57212cc-6704-4bc8-9853-17a2e6cad72a' User entered '08 Apr 2021 12:00:28'	System	08 Apr 2021 17:00:42
	System	08 Apr 2021 17:00:42

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '05 Apr 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '09 Apr 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-04-14T09:59:28-05:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'acccee55-c595-4346-85ee-9bd3f48c7ed9' User entered 'No (N)'	System	14 Apr 2021 14:59:55
	System	14 Apr 2021 14:59:55

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-04-14T09:59:33-05:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'acccee55-c595-4346-85ee-9bd3f48c7ed9'	System	14 Apr 2021 14:59:55
User entered 'No (N)'	System	14 Apr 2021 14:59:55

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-04-14T09:59:42-05:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'acccee55-c595-4346-85ee-9bd3f48c7ed9' User entered '14 Apr 2021 09:59:42'	System	14 Apr 2021 14:59:55
	System	14 Apr 2021 14:59:55

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '12 Apr 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '16 Apr 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-04-21T10:00:28-05:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '2711d7ac-c0fa-4935-80a7-6a2ad3d85560' User entered 'No (N)'	System	21 Apr 2021 15:00:40
	System	21 Apr 2021 15:00:40

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-04-21T10:00:31-05:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '2711d7ac-c0fa-4935-80a7-6a2ad3d85560' User entered 'No (N)'	System	21 Apr 2021 15:00:40
	System	21 Apr 2021 15:00:40

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-04-21T10:00:35-05:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '2711d7ac-c0fa-4935-80a7-6a2ad3d85560' User entered '21 Apr 2021 10:00:35'	System	21 Apr 2021 15:00:40
	System	21 Apr 2021 15:00:40

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '19 Apr 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '23 Apr 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-04-28T10:00:27-05:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '20d06b66-42f5-471e-8bd3-392926bf489e' User entered 'No (N)'	System	28 Apr 2021 22:11:45
	System	28 Apr 2021 22:11:45

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-04-28T10:00:30-05:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '20d06b66-42f5-471e-8bd3-392926bf489e' User entered 'No (N)'	System	28 Apr 2021 22:11:45
	System	28 Apr 2021 22:11:45

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-04-28T10:00:35-05:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '20d06b66-42f5-471e-8bd3-392926bf489e' User entered '28 Apr 2021 10:00:35'	System	28 Apr 2021 22:11:45
	System	28 Apr 2021 22:11:45

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '26 Apr 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '30 Apr 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '03 May 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '07 May 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '10 May 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '14 May 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '17 May 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '21 May 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '24 May 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '28 May 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '31 May 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '04 Jun 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '07 Jun 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '11 Jun 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '14 Jun 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '18 Jun 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '21 Jun 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '25 Jun 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '28 Jun 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '02 Jul 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '05 Jul 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '09 Jul 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '12 Jul 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '16 Jul 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '19 Jul 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '23 Jul 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '26 Jul 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '30 Jul 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '02 Aug 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '06 Aug 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '09 Aug 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '13 Aug 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '16 Aug 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '20 Aug 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '23 Aug 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '27 Aug 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '30 Aug 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '03 Sep 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '06 Sep 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '10 Sep 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '13 Sep 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '17 Sep 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '20 Sep 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '24 Sep 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '27 Sep 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '01 Oct 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '04 Oct 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '08 Oct 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '11 Oct 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '15 Oct 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '18 Oct 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '22 Oct 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '25 Oct 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '29 Oct 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '01 Nov 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '05 Nov 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '08 Nov 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '12 Nov 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '15 Nov 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '19 Nov 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '22 Nov 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '26 Nov 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '29 Nov 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '03 Dec 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '06 Dec 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '10 Dec 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '13 Dec 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '17 Dec 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '20 Dec 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '24 Dec 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '27 Dec 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '31 Dec 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '03 Jan 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '07 Jan 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '10 Jan 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '14 Jan 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '17 Jan 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '21 Jan 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '24 Jan 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '28 Jan 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '31 Jan 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '04 Feb 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '07 Feb 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '11 Feb 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '14 Feb 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '18 Feb 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '21 Feb 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '25 Feb 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '28 Feb 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '04 Mar 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '07 Mar 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '11 Mar 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '14 Mar 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '18 Mar 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '21 Mar 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '25 Mar 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '28 Mar 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '01 Apr 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '04 Apr 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '08 Apr 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '11 Apr 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '15 Apr 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '18 Apr 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '22 Apr 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '25 Apr 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '29 Apr 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '02 May 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '06 May 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '09 May 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '13 May 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '16 May 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '20 May 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '23 May 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '27 May 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '30 May 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '03 Jun 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '06 Jun 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '10 Jun 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '13 Jun 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '17 Jun 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '20 Jun 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '24 Jun 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '27 Jun 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '01 Jul 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '04 Jul 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '08 Jul 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '11 Jul 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '15 Jul 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '18 Jul 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '22 Jul 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '25 Jul 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '29 Jul 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '01 Aug 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '05 Aug 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '08 Aug 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '12 Aug 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '15 Aug 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '19 Aug 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '22 Aug 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '26 Aug 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '29 Aug 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '02 Sep 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '05 Sep 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '09 Sep 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '12 Sep 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '16 Sep 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '19 Sep 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '23 Sep 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '26 Sep 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '30 Sep 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '03 Oct 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '07 Oct 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '10 Oct 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '14 Oct 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '17 Oct 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '21 Oct 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '24 Oct 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '28 Oct 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '31 Oct 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '04 Nov 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:27:54

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-03-03T12:02:04-06:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f5c5d1fb-15d2-4d1a-878a-41512a57596b'	System	03 Mar 2021 18:05:25
User entered 'No (N)'	System	03 Mar 2021 18:05:25

US3292365

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:27:54

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2021-03-03T12:02:12-06:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f5c5d1fb-15d2-4d1a-878a-41512a57596b' User entered '03 Mar 2021 12:02:12'	System	03 Mar 2021 18:05:25
	System	03 Mar 2021 18:05:25

US3292365

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 22:30:23

US3292365

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '20 Nov 2020'	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 22:30:23

US3292365

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 22:30:23

US3292365

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 22:30:23

US3292365

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 22:30:28

US3292365

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:18
User entered 'l'	System	23 Nov 2020 22:30:28

US3292365

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:03:32
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Dec 2020 20:34:43

US3292365

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:03:32
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '23 Dec 2020'	(b) (4), (b) (6)	28 Dec 2020 20:34:43

US3292365

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:03:32
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Dec 2020 20:34:43

US3292365

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:03:32
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4), (b) (6)	28 Dec 2020 20:34:43

US3292365

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:03:32
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Dec 2020 20:34:47

US3292365

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:03:32
User entered 'l'	System	28 Dec 2020 20:34:47

US3292365

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:03:32
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Jan 2021 18:15:46

US3292365

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:03:32
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '22 Jan 2021'	(b) (4), (b) (6)	26 Jan 2021 18:15:46

US3292365

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:03:32
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	26 Jan 2021 18:15:46

US3292365

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:03:32
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 18:15:46

US3292365

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:03:32
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Jan 2021 18:15:52

US3292365

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:03:32
User entered 'l'	System	26 Jan 2021 18:15:52

US3292365

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:03:32
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:22:13
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	24 Feb 2021 16:39:57

US3292365

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:03:32
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:22:13
User entered '23 Feb 2021'	(b) (4) Gerardo Pena (b) (4)	24 Feb 2021 16:39:57

US3292365

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:03:32
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:22:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gerardo Pena (b) (4)	24 Feb 2021 16:39:57

US3292365

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:03:32
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:22:13
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	24 Feb 2021 16:39:57

US3292365

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:03:32
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:22:13
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	24 Feb 2021 16:39:46

US3292365

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:03:32
User entered 'l'	System	24 Feb 2021 16:39:46

US3292365

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:51:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Mar 2021 13:36:44

US3292365

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:54

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:51:55
User entered '22 Mar 2021'	(b) (4), (b) (6)	23 Mar 2021 13:36:44

US3292365

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:54

[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 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:51:55
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	23 Mar 2021 13:36:44

US3292365

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'VISIT4'	System	23 Mar 2021 13:36:44

US3292365

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:51:55
User entered 'No (N)'	(b) (4), (b) (6)	31 Mar 2021 19:02:57

US3292365

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:51:55
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:02:57

US3292365

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:51:55
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:02:57

US3292365

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered empty.	System	31 Mar 2021 19:02:57

US3292365

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:51:55
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:02:57

US3292365

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:51:55
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:02:57

US3292365

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:51:55
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:02:57

US3292365

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:51:55
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:02:57

US3292365

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered empty.	System	31 Mar 2021 19:02:57

US3292365

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:51:55
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:02:57

US3292365

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered empty.	System	31 Mar 2021 19:02:57

US3292365

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:51:55
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:02:57

US3292365

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered empty.	System	31 Mar 2021 19:02:57

US3292365

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:51:55
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:02:57

US3292365

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered empty.	System	31 Mar 2021 19:02:57

US3292365

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29

US3292365

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:54

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29

US3292365

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:27:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'No (N)'	(b) (4), (b) (6)	23 Mar 2021 13:36:50

US3292365

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:27:54

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4), (b) (6)	23 Mar 2021 13:36:50

US3292365

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Mar 2021 13:37:15

US3292365

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:54

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered '22 Mar 2021'	(b) (4), (b) (6)	23 Mar 2021 13:37:15

US3292365

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:54

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered '13:47'	(b) (4), (b) (6)	23 Mar 2021 13:37:15

US3292365

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered '22 Mar 2021 13:47'	System	23 Mar 2021 13:37:15

US3292365

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Mar 2021 13:37:19

US3292365

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:23:29
User entered 'I'	System	23 Mar 2021 13:37:19

US3292365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:15
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4) Kevin Martinez (b) (4)	02 Feb 2021 19:46:41

US3292365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:54

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:15
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '2 Feb 2021'	(b) (4) Kevin Martinez (b) (4)	02 Feb 2021 19:46:41

US3292365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:54

[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 20:40:15
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Clinic (Clinic)'	(b) (4) Kevin Martinez (b) (4)	02 Feb 2021 19:46:41

US3292365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:15
User entered 'UNBLND_DECIDE'	System	02 Feb 2021 19:46:41

US3292365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:27:54

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:15
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '2 Feb 2021'	(b) (4) Kevin Martinez (b) (4)	02 Feb 2021 19:46:58

US3292365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:27:54

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:15
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:28:29

US3292365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:27:54

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:15
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4) Kevin Martinez (b) (4)	02 Feb 2021 19:46:58

US3292365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:27:54

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:15
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:28:29

US3292365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:27:54

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:15
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '2 Feb 2021'	(b) (4) Kevin Martinez (b) (4)	02 Feb 2021 19:46:58

US3292365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:27:54

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:15
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Kevin Martinez (b) (4)	02 Feb 2021 19:46:58

US3292365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:27:54

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:15
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Kevin Martinez (b) (4)	02 Feb 2021 19:46:58

US3292365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:27:54

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:15
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Kevin Martinez (b) (4)	02 Feb 2021 19:46:58

US3292365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:27:54

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:15
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'No (N)'	(b) (4) Kevin Martinez (b) (4)	02 Feb 2021 19:46:58

US3292365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:27:54

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:15
User entered empty.	System	02 Feb 2021 19:46:58

US3292365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:27:54

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:15
User entered empty.	System	02 Feb 2021 19:46:58

US3292365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:15
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4) Kevin Martinez (b) (4)	02 Feb 2021 19:47:24

US3292365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:54

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:15
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '2 Feb 2021'	(b) (4) Kevin Martinez (b) (4)	02 Feb 2021 19:47:24

US3292365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:54

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:15
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '11:12'	(b) (4) Kevin Martinez (b) (4)	02 Feb 2021 19:47:24

US3292365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:15
User entered '2 Feb 2021 11:12'	System	02 Feb 2021 19:47:24

US3292365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:27:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:15
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4) Kevin Martinez (b) (4)	02 Feb 2021 19:47:35

US3292365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:27:54

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:15
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '2 Feb 2021'	(b) (4) Kevin Martinez (b) (4)	02 Feb 2021 19:47:35

US3292365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:27:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:15
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '11:30'	(b) (4) Kevin Martinez (b) (4)	02 Feb 2021 19:47:35

US3292365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:27:54

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:15
User entered '2 Feb 2021 11:30'	System	02 Feb 2021 19:47:35

US3292365

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:27:54

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:38
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4) Antonio Gutierrez (b) (4)	09 Nov 2020 20:08:38

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:54

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
DataPoint Verified.	(b) (4)	23 Nov 2020 18:42:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:39:52
User entered	System	10 Nov 2020 23:39:46
'USA-US072-2020-mRNA-1273-P301000010'		
User entered 'New'	(b) (4), (b) (6)	10 Nov 2020 23:39:46

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:54

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Nov 2020 16:58:46
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Invasive lobular breast carcinoma, LLT: Invasive lobular breast carcinoma - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 20:12:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 20:12:20
Data point term sent to Coder	System	23 Nov 2020 19:40:38
User closed query 'CDM Coding: Please update the term if it means 'Invasive lobular breast carcinoma', else please clarify.' (Site from System).	System	23 Nov 2020 19:40:24
Query 'CDM Coding: Please update the term if it means 'Invasive lobular breast carcinoma', else please clarify.' answered with 'updated' (Site from System).	Antonio Gutierrez (b) (4)	23 Nov 2020 19:40:24
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	23 Nov 2020 19:40:16
User entered 'INVASIVE LOBULAR BREAST CARCINOMA' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	23 Nov 2020 19:40:16
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:44:22
User opened query 'CDM Coding: Please update the term if it means 'Invasive lobular breast carcinoma', else please clarify.' (Site from System).	Coder Import (b) (4)	12 Nov 2020 03:43:40
Data point term sent to Coder	System	09 Nov 2020 21:53:39
User entered 'Invasive LOBULAR CARCINOMA' reason for change: New Information	Antonio Gutierrez (b) (4)	09 Nov 2020 21:53:37
Data point term sent to Coder	System	09 Nov 2020 20:48:39
User entered 'Gladular Lobular Carcinoma'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:43:30
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

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Folder: Adverse Events

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:43:31
User entered 'No (N)'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:43:32
User entered 'No (N)'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

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Folder: Adverse Events

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
User closed query 'Start date does not match start date per source. Please review source and update.' (Site from CRA).	(b) (4), (b) (6)	23 Feb 2021 01:11:44
Query 'Start date does not match start date per source. Please review source and update.' answered with 'date now matches source' (Site from CRA).		18 Feb 2021 20:26:24
User entered '9 Nov 2020' reason for change: Per Query Resolution		26 Jan 2021 18:18:29
User opened query 'Start date does not match start date per source. Please review source and update.' (Site from CRA).		25 Nov 2020 17:12:01
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	24 Nov 2020 22:56:39
User entered '08 Oct 2020' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	24 Nov 2020 22:56:39
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:43:34
User entered '9 Nov 2020'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

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Folder: Adverse Events

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Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:43:35
User entered empty.	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

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Folder: Adverse Events

Form: Adverse Events (1)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 20:48:20

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Form: Adverse Events (1)

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
DataPoint Un-verified.	(b) (4)	26 Jan 2021 18:18:29
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 18:18:29
DataPoint Verified.		23 Nov 2020 18:43:36
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

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Folder: Adverse Events

Form: Adverse Events (1)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 18:18:29
User entered '14 Jan 2021' reason for change: Data Entry Error		26 Jan 2021 18:18:29
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		25 Nov 2020 20:49:40
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Event ongoing. Double mastectomy scheduled for 14DEC2020.' (Site from Safety).	Antonio Gutierrez (b) (4)	24 Nov 2020 22:59:36
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:43:38
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		19 Nov 2020 18:13:27
User entered empty.	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:54

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:43:39
User entered empty.	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

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Folder: Adverse Events

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date, when available. ' canceled (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 18:10:44
User opened query 'PV Query: Please provide the event end date, when available. ' (Site from Safety).		04 Dec 2020 21:18:18
User entered empty.	System	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:43:41
User entered 'Grade 3/Severe (Grade 3/Severe)'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:43:42
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:43:46
User entered '0'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:43:47
User entered '0'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:43:49
User entered '0'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:43:50
User entered empty.	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:43:51
User entered empty.	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:43:53
User entered empty.	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:43:54
User entered empty.	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

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Folder: Adverse Events

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:43:57
User entered '0'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:43:56
User entered '0'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

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Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:43:59
User entered 'I'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:44:00
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:44:02
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:44:05
User entered 'Not Applicable (NOT APPLICABLE)'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

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None

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded for this condition which is unexpected. Please review and ensure that CM/ConProc for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM). Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded for this condition which is unexpected. Please review and ensure that CM/ConProc for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'updated' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	19 Feb 2021 14:01:29
		19 Feb 2021 02:20:16
		19 Feb 2021 02:19:35
User entered '0' reason for change: Per Query Resolution		19 Feb 2021 02:19:35
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded for this condition which is unexpected. Please review and ensure that CM/ConProc for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM). DataPoint Verified.		08 Dec 2020 06:14:04
		25 Nov 2020 17:08:10
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	24 Nov 2020 22:37:48
User entered '1' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	24 Nov 2020 22:37:48
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:44:06
User entered '0' reason for change: New Information	Antonio Gutierrez (b) (4)	09 Nov 2020 21:53:37
User entered '1'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:44:08
User entered '0'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
Un-reviewed for Data Management.	(b) (4)	19 Feb 2021 02:19:35
DataPoint Un-verified.	(b) (4), (b) (6)	19 Feb 2021 02:19:35
User entered '1' reason for change: Per Query Resolution		19 Feb 2021 02:19:35
Reviewed for Data Management.		16 Dec 2020 10:04:50
DataPoint Verified.		25 Nov 2020 17:08:13
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).		25 Nov 2020 15:09:06
Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' answered with 'updated' (Site from DM).	Antonio Gutierrez (b) (4)	24 Nov 2020 22:39:40
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	24 Nov 2020 22:37:48
User entered '0' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	24 Nov 2020 22:37:48
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 00:01:59
DataPoint Verified.		23 Nov 2020 18:44:09
User entered '1' reason for change: New Information	Antonio Gutierrez (b) (4)	09 Nov 2020 21:53:37
User entered '0'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
User closed query 'PV Query: Please provide the final outcome, when available. ' (Site from Safety).	(b) (4)	22 Feb 2021 15:12:41
Query 'PV Query: Please provide the final outcome, when available. ' answered with 'provided' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 02:19:09
DataPoint Un-verified.		26 Jan 2021 18:18:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error		26 Jan 2021 18:18:29
User opened query 'PV Query: Please provide the final outcome, when available. ' (Site from Safety).		04 Dec 2020 21:18:00
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		25 Nov 2020 20:49:47
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Event ongoing. Double mastectomy scheduled for 14DEC2020.' (Site from Safety).	Antonio Gutierrez (b) (4)	24 Nov 2020 23:00:03
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:44:12
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		19 Nov 2020 18:13:44
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:44:13
User entered empty.	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e. additional scans). Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety). Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e. additional scans). Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' answered with 'Medical records have been sent to email inbox' (Site from Safety). User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e. additional scans). Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety). User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e. additional scans). Please include units and reference ranges if applicable. ' (Site from Safety). Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e. additional scans). Please include units and reference ranges if applicable. ' answered with 'Please advise on where to add these results.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 13:10:31
		30 Apr 2021 18:24:47
		02 Mar 2021 18:11:27
		02 Mar 2021 17:37:08
	Victoria Hernandez (b) (4)	01 Mar 2021 18:11:09

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative = PATIENT CONTACTED STUDY STAFF THIS AFTERNOON (09NOV2020) TO INFORM THE STUDY TEAM THAT SHE HAD RECEIVED THE RESULTS OF HER ANNUAL MAMMOGRAM, COMPLETED LAST WEEK. Please review and determine if the start date of this AE should be reconciled as it mentioned that on 09NOV2020, the site was informed that the MAMMOGRAM was completed "LAST WEEK". Verify and update as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 06:34:26
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e. additional scans). Please include units and reference ranges if applicable. ' (Site from Safety).		04 Dec 2020 21:18:35
User closed query 'PV Query: Please report if the patient has any family history or risk factors for development of breast cancer.' (Site from Safety).		25 Nov 2020 20:50:42
User closed query 'PV Query: Has the subject seen an oncologist or have plans to see one? If so, please provide oncology consultation notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).		25 Nov 2020 20:50:32
User closed query 'PV Query: Please consider updating start date to date of mammogram.' (Site from Safety).		25 Nov 2020 20:50:25
User closed query 'PV Query: Please provide the date the subject underwent mammogram.' (Site from Safety).		25 Nov 2020 20:50:10
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e. additional scans). Please include units and reference ranges if applicable' (Site from Safety).		25 Nov 2020 20:50:02

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 20:49:55
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e. additional scans). Please include units and reference ranges if applicable' answered with 'Medical records to be requested. No new information available at this time.' (Site from Safety).	Antonio Gutierrez (b) (4)	24 Nov 2020 23:00:45
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Double mastectomy scheduled for 14DEC2020.' (Site from Safety).	Antonio Gutierrez (b) (4)	24 Nov 2020 23:00:21
Query 'Per DM CLR: SAE Narrative = PATIENT CONTACTED STUDY STAFF THIS AFTERNOON (09NOV2020) TO INFORM THE STUDY TEAM THAT SHE HAD RECEIVED THE RESULTS OF HER ANNUAL MAMMOGRAM, COMPLETED LAST WEEK. Please review and determine if the start date of this AE should be reconciled as it mentioned that on 09NOV2020, the site was informed that the MAMMOGRAM was completed "LAST WEEK". Verify and update as appropriate. Otherwise, clarify. ' answered with 'dates updated' (Site from DM).	Antonio Gutierrez (b) (4)	24 Nov 2020 22:58:56
Query 'PV Query: Please report if the patient has any family history or risk factors for development of breast cancer.' answered with 'Patient states (b) (6) and (b) (6) both had breast cancer. Additionally, (b) (6) had breast cancer as well. ' (Site from Safety).	Antonio Gutierrez (b) (4)	24 Nov 2020 22:58:43

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Has the subject seen an oncologist or have plans to see one? If so, please provide oncology consultation notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.'	Antonio Gutierrez (b) (4)	24 Nov 2020 22:57:27
answered with 'Patient has not seen oncologist. Plans to have double mastectomy first' (Site from Safety).		
Query 'PV Query: Please consider updating start date to date of mammogram.' answered with 'updated' (Site from Safety).	Antonio Gutierrez (b) (4)	24 Nov 2020 22:56:58
Query 'PV Query: Please provide the date the subject underwent mammogram.' answered with 'First mammogram 08OCT2020. Confirmatory mammogram on 29OCT2020.' (Site from Safety).	Antonio Gutierrez (b) (4)	24 Nov 2020 22:55:58
User opened query 'Per DM CLR: SAE Narrative = PATIENT CONTACTED STUDY STAFF THIS AFTERNOON (09NOV2020) TO INFORM THE STUDY TEAM THAT SHE HAD RECEIVED THE RESULTS OF HER ANNUAL MAMMOGRAM, COMPLETED LAST WEEK. Please review and determine if the start date of this AE should be reconciled as it mentioned that on 09NOV2020, the site was informed that the MAMMOGRAM was completed "LAST WEEK". Verify and update as appropriate. Otherwise, clarify. (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:02:33
		23 Nov 2020 18:44:15
User opened query 'PV Query: Please report if the patient has any family history or risk factors for development of breast cancer.' (Site from Safety).		19 Nov 2020 18:16:58
User opened query 'PV Query: Has the subject seen an oncologist or have plans to see one? If so, please provide oncology consultation notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).		19 Nov 2020 18:16:38
User opened query 'PV Query: Please consider updating start date to date of mammogram.' (Site from Safety).		19 Nov 2020 18:16:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:54

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the date the subject underwent mammogram.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 18:14:39
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e. additional scans). Please include units and reference ranges if applicable' (Site from Safety).		19 Nov 2020 18:14:25
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		19 Nov 2020 18:14:12
User entered 'PATIENT CONTACTED STUDY STAFF THIS AFTERNOON (09NOV2020) TO INFORM THE STUDY TEAM THAT SHE HAD RECEIVED THE RESULTS OF HER ANNUAL MAMMOGRAM, COMPLETED LAST WEEK. AS PER THE PATIENT, SHE WAS DIAGNOSED WITH A GLANDULAR LOBULAR CARCINOMA IN HER LEFT BREAST. PATIENT STATES SHE NEVER FELT A LUMP, NOR DOES SHE FEEL ONE NOW. THE CARCINOMA WAS DISCOVERED VIA THE MAMMOGRAM. AT THIS TIME, PATIENT STATES THAT SHE DOES NOT WANT TO PUT HERSELF THROUGH RADIATION OR CHEMOTHERAPY AND PLANS TO HAVE A TOTAL MASTECTOMY DONE. PATIENT HAS A FOLLOW-UP SURGERY CONSULT SCHEDULED AND WILL FOLLOW UP WITH STUDY STAFF IN REGARDS TO HER TREATMENT PLAN.' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	09 Nov 2020 20:50:17

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:54

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Patient contacted study staff this afternoon (09NOV2020) to inform the study team that she had received the results of her annual mammogram, completed last week. As per the patient, she was diagnosed with a glandular lobular carcinoma in her left breast. Patient states she never felt a lump, nor does she feel one now. The carcinoma was discovered via the mammogram. At this time, patient states that she does not want to put herself through radiation or chemotherapy and plants to have a total mastectomy done. Patient has a follow-up surgery consult scheduled and will follow up with study staff in regards to her treatment plan.'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:54

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'l'	System	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:54

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:54

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Eye and eyelid infections, PT: Conjunctivitis, LLT: Conjunctivitis - version MedDRA\\23.0.	Coder Import (b) (4)	25 Feb 2021 20:56:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Feb 2021 20:56:01
Data point term sent to Coder	System	25 Feb 2021 20:55:04
User entered 'Conjunctivitis'	Gerardo Pena (b) (4)	25 Feb 2021 20:54:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	25 Feb 2021 20:54:17

US3292365

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:54

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Feb 2021 20:54:17

US3292365

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Feb 2021 20:54:17

US3292365

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
User entered '23 Feb 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Feb 2021 20:54:17

US3292365

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:54

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Feb 2021 20:54:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:54

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 20:54:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:31
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	03 May 2021 19:15:34
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Gerardo Pena (b) (4)	03 May 2021 19:15:34
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
	(b) (4)	
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	25 Feb 2021 20:54:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:54

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:31
	(b) (4)	
Signature has been broken.	Gerardo Pena (b) (4)	03 May 2021 19:15:34
	(b) (4)	
User entered '8 Mar 2021' reason for change: New Information	Gerardo Pena (b) (4)	03 May 2021 19:15:34
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
	(b) (4)	
User entered empty.	Gerardo Pena (b) (4)	25 Feb 2021 20:54:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:54

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Feb 2021 20:54:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:54

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 20:54:17

US3292365

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:54

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Feb 2021 20:54:17

US3292365

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Feb 2021 20:54:17

US3292365

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:54

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Feb 2021 20:54:17

US3292365

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Feb 2021 20:54:17

US3292365

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Feb 2021 20:54:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:54

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Feb 2021 20:54:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:54

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Feb 2021 20:54:17

US3292365

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:54

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Feb 2021 20:54:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:54

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Feb 2021 20:54:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Feb 2021 20:54:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Feb 2021 20:54:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Feb 2021 20:54:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:54

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Mar 2021 18:10:30
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	01 Mar 2021 18:10:30
User opened query 'Data is required. Please complete.' (Site from System).	Victoria Hernandez (b) (4)	01 Mar 2021 18:10:30
User entered empty.	(b) (4)	
	System	25 Feb 2021 20:54:17
	Gerardo Pena (b) (4)	25 Feb 2021 20:54:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:54

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Mar 2021 18:10:30
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	01 Mar 2021 18:10:30
User opened query 'Data is required. Please complete.' (Site from System).	Victoria Hernandez (b) (4)	01 Mar 2021 18:10:30
User entered empty.	(b) (4)	
	System	25 Feb 2021 20:54:17
	Gerardo Pena (b) (4)	25 Feb 2021 20:54:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:54

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
User entered 'None (NONE)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Feb 2021 20:54:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:54

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Feb 2021 20:54:17

US3292365

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:54

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
User closed query 'Per CDM: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:25:09
Query 'Per CDM: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'there is an AE for this??' (Site from DM).	Dawn Killian (b) (4) (b) (4)	13 Apr 2021 21:59:22
User opened query 'Per CDM: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 08:39:24
User entered 'I'	Gerardo Pena (b) (4) (b) (4)	25 Feb 2021 20:54:17

US3292365

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:54

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Feb 2021 20:54:17

US3292365

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:54

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:31
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	03 May 2021 19:15:34
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Gerardo Pena (b) (4)	03 May 2021 19:15:34
New Information	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Gerardo Pena (b) (4)	25 Feb 2021 20:54:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:54

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Feb 2021 20:54:17

US3292365

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:54

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:47
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Feb 2021 20:54:17

US3292365

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:54

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Feb 2021 20:54:17

US3292365

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:54

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	25 Feb 2021 20:54:17

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:27:54

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:38
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 03:50:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:54

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:07
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
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)	01 Sep 2020 03:58:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Sep 2020 03:58:46
Data point term sent to Coder	System	01 Sep 2020 03:52:10
User entered 'aspirin'	(b) (4), (b) (6)	01 Sep 2020 03:51:37

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:07
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:51:37

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:07
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'Prophylaxis for cardiac preventative'	(b) (4), (b) (6)	01 Sep 2020 03:51:37

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:07
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered '81'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:51:37

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:07
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:51:37

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:07
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:51:37

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:07
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:51:37

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:07
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:51:37

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:07
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Sep 2020 03:51:37

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:07
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:51:37

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:07
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'un UNK 2010'	(b) (4), (b) (6)	01 Sep 2020 03:51:37

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:07
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:51:37

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:07
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Gerardo Pena (b) (4)	17 Nov 2020 22:46:18
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	01 Sep 2020 03:51:37

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:07
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	16 Apr 2021 14:48:58
User entered '11 Nov 2020' reason for change: New Information	Gerardo Pena (b) (4) (b) (4)	17 Nov 2020 22:46:18
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:51:37

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:07
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 03:51:37

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:07
User entered 'I'	System	01 Sep 2020 03:51:37

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:07
User entered 'I'	System	01 Sep 2020 03:51:37

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:07
User entered '804 (804)'	System	01 Sep 2020 03:51:37

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
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.	(b) (4) Coder Import (b) (4)	01 Sep 2020 08:50:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 08:50:43
Data point term sent to Coder	System	01 Sep 2020 03:53:11
User entered 'Vitamin C'	(b) (4), (b) (6)	01 Sep 2020 03:52:25

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User closed query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 03:42:55
Query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' answered with 'updated' (Site from DM).	Gerardo Pena (b) (4)	29 Dec 2020 23:06:47
User entered 'Yes (Y)' reason for change: Data Entry Error	Gerardo Pena (b) (4)	29 Dec 2020 23:06:39
User opened query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:01:54
User entered 'No (N)'		01 Sep 2020 03:52:25

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'general health suppliment'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:52:25

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered '1000'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:52:25

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:52:25

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:52:25

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:52:25

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:52:25

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:52:25

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:52:25

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:54

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'un Aug 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:52:25

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:52:25

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:52:25

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:52:25

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:52:25

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 03:52:25

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Sep 2020 03:52:25

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 03:52:25

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Mar 2021 05:48:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Mar 2021 05:48:05
Data point term sent to Coder Coding entries removed.	System	26 Mar 2021 14:51:18
	Nathan Cortez (b) (4)	26 Mar 2021 14:50:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 03:59:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 03:59:47
Data point term sent to Coder	System	01 Sep 2020 03:55:13
User entered 'aspirin'	(b) (4), (b) (6)	01 Sep 2020 03:54:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User closed query 'Per DM CLR: Prophylaxis=Yes. Please review if this indication should be changed to MH as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update this field to No as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 09:07:06
Query 'Per DM CLR: Prophylaxis=Yes. Please review if this indication should be changed to MH as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update this field to No as appropriate. Else, clarify. ' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	13 Apr 2021 21:59:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	13 Apr 2021 21:59:47
User opened query 'Per DM CLR: Prophylaxis=Yes. Please review if this indication should be changed to MH as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update this field to No as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 12:55:52
User entered 'Yes (Y)'		01 Sep 2020 03:54:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User closed query 'Per DM CLR: Please update the indication to reflect the location (bilateral, left, right) and/or type of PROPHYLAXIS FOR PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 09:06:26
Query 'Per DM CLR: Please update the indication to reflect the location (bilateral, left, right) and/or type of PROPHYLAXIS FOR PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'Updated term' (Site from DM).	Nathan Cortez (b) (4)	26 Mar 2021 14:50:24
User entered 'General Aches' reason for change: Data Entry Error	Nathan Cortez (b) (4)	26 Mar 2021 14:50:18
User opened query 'Per DM CLR: Please update the indication to reflect the location (bilateral, left, right) and/or type of PROPHYLAXIS FOR PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 04:02:31
User entered 'Prophylaxis for pain'		01 Sep 2020 03:54:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered '500'	(b) (4), (b) (6)	01 Sep 2020 03:54:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:54:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:54:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:54:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:54:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Sep 2020 03:54:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:54:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'un Aug 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:54:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 03:54:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Gerardo Pena (b) (4)	17 Nov 2020 22:45:48
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	01 Sep 2020 03:54:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered '11 Nov 2020' reason for change: Data Entry Error	(b) (4)	17 Nov 2020 22:45:48
User entered empty.	Gerardo Pena (b) (4)	01 Sep 2020 03:54:24
	(b) (4), (b) (6)	

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 03:54:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:16
User entered empty.	System	01 Sep 2020 03:54:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:16
User entered empty.	System	01 Sep 2020 03:54:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:16
User entered empty.	System	01 Sep 2020 03:54:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Sep 2020 08:53:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 08:53:48
Data point term sent to Coder	System	01 Sep 2020 03:55:15
User entered 'zinc'	(b) (4), (b) (6)	01 Sep 2020 03:55:07

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User closed query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 03:42:32
Query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' answered with 'updated' (Site from DM).	Gerardo Pena (b) (4)	29 Dec 2020 23:07:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Gerardo Pena (b) (4)	29 Dec 2020 23:07:06
User opened query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:01:08
User entered 'No (N)'		01 Sep 2020 03:55:07

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'general health suppliment'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:55:07

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:01:12
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'unknown per patient' (Site from DM).		23 Sep 2020 14:45:29
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).		23 Sep 2020 04:37:14
User entered 'I'		01 Sep 2020 03:55:07

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:55:07

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:55:07

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:55:07

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:55:07

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:55:07

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:55:07

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:54

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'un Jul 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:55:07

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:55:07

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:55:07

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:55:07

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:55:07

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 03:55:07

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 03:55:07

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 03:55:07

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: DULOXETINE HYDROCHLORIDE, PRODUCTSYNONYM: DULOXETINE HCL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Sep 2020 05:53:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 05:53:47
Data point term sent to Coder	System	01 Sep 2020 03:57:16
User entered 'duloxetine hcl dr'	(b) (4), (b) (6)	01 Sep 2020 03:56:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:56:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'anxiety'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:56:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered '60'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:56:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:56:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:56:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:56:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:56:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:56:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:56:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:54

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:56:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:56:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:56:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:56:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:56:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	01 Sep 2020 03:56:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Sep 2020 03:56:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 03:56:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST SODIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Sep 2020 03:58:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 03:58:46
Data point term sent to Coder	System	01 Sep 2020 03:58:17
User entered 'montelukast sodium'	(b) (4), (b) (6)	01 Sep 2020 03:57:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:57:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'asthma'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:57:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered '10'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:57:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:57:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:57:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:57:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:57:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:57:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:57:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
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)	11 Nov 2020 15:04:08
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 'unable to clarify, patient did not answer' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 14:46:48
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).		23 Sep 2020 03:59:37
User entered 'un UNK 2005'		01 Sep 2020 03:57:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:57:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:57:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:57:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:57:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Sep 2020 03:57:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Sep 2020 03:57:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 03:57:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL SULFATE, PRODUCTSYNONYM: PROAIR RESPICLICK - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	24 Sep 2020 11:30:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 11:30:53
Data point term sent to Coder	System	23 Sep 2020 14:47:44
Coding entries removed.	(b) (4), (b) (6)	23 Sep 2020 14:47:03
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL SULFATE, PRODUCTSYNONYM: PROAIR RESPICLICK - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 08:33:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 08:33:52
Data point term sent to Coder	System	01 Sep 2020 04:00:19
User entered 'proair respiclick'	(b) (4), (b) (6)	01 Sep 2020 03:59:56

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:59:56

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead of the DRUG ACTION/CLASS. Please reconcile with AE or Med History eCRF so there is an appropriate match.' (Site from DM).	(b) (4)	07 Oct 2020 15:06:06
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead of the DRUG ACTION/CLASS. Please reconcile with AE or Med History eCRF so there is an appropriate match.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 14:47:13
User entered 'asthma' reason for change: Data Entry Error		23 Sep 2020 14:47:03
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead of the DRUG ACTION/CLASS. Please reconcile with AE or Med History eCRF so there is an appropriate match.' (Site from DM).		23 Sep 2020 04:14:13
User entered 'rescue inhaler'		01 Sep 2020 03:59:56

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered '90'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:59:56

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'ug (ug)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:59:56

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:59:56

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:59:56

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:59:56

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:59:56

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:59:56

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
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)	
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 'asthma data corrected and updated' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:04:18
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).	Kevin Martinez (b) (4)	05 Nov 2020 19:16:25
User entered 'un UNK 2005'	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 03:53:13
		01 Sep 2020 03:59:56

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:59:56

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:59:56

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:59:56

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:59:56

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 03:59:56

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 03:59:56

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 03:59:56

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE FUROATE, PRODUCTSYNONYM: ARNUITY ELLIPTA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Sep 2020 04:02:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 04:02:38
Data point term sent to Coder	System	01 Sep 2020 04:02:20
User entered 'arnuity ellipta'	(b) (4), (b) (6)	01 Sep 2020 04:01:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:01:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'asthma'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:01:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered '100'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:01:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'ug (ug)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:01:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:01:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:01:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:01:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:01:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:01:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:54

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:01:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:01:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:01:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:01:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:01:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Sep 2020 04:01:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Sep 2020 04:01:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 04:01:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: SUMATRIPTAN SUCCINATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Sep 2020 06:39:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 06:39:45
Data point term sent to Coder	System	01 Sep 2020 04:02:22
User entered 'sumatriptan succinate'	(b) (4), (b) (6)	01 Sep 2020 04:02:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:02:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'migraine'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:02:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered '100'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:02:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:02:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:02:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:02:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:02:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:02:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:02:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:54

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:02:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:02:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:02:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:02:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:02:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 04:02:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 04:02:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 04:02:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:27:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:22
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: PROGESTOGENS, ATC: PREGNEN (4) DERIVATIVES, PRODUCT: PROGESTERONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Sep 2020 04:03:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 04:03:40
Data point term sent to Coder	System	01 Sep 2020 04:03:23
User entered 'progesterone'	(b) (4), (b) (6)	01 Sep 2020 04:02:54

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:27:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:22
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:02:54

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:27:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:22
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'hot flashes'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:02:54

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:27:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:22
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered '200'	(b) (4), (b) (6)	01 Sep 2020 04:02:54

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:27:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:22
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Sep 2020 04:02:54

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:27:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:22
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:02:54

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:27:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:22
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:02:54

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:27:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:22
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:02:54

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:27:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:22
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Sep 2020 04:02:54

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:27:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:22
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:02:54

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:27:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:22
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'un UNK 2014'	(b) (4), (b) (6)	01 Sep 2020 04:02:54

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:22
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:02:54

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:27:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:22
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Gerardo Pena (b) (4)	17 Nov 2020 22:47:22
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	01 Sep 2020 04:02:54

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:27:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:22
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered '12 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Gerardo Pena (b) (4)	17 Nov 2020 22:47:22
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	01 Sep 2020 04:02:54

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:27:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:22
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:02:54

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:27:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:22
User entered 'I'	System	01 Sep 2020 04:02:54

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:27:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:22
User entered 'I'	System	01 Sep 2020 04:02:54

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:27:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:22
User entered '804 (804)'	System	01 Sep 2020 04:02:54

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:27:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:25
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Sep 2020 04:05:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 04:05:42
Data point term sent to Coder	System	01 Sep 2020 04:04:23
User entered 'estradiol'	(b) (4), (b) (6)	01 Sep 2020 04:04:16

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:27:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:25
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:04:16

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:27:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:25
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 15:06:38
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'added to med Hx' (Site from DM).		23 Sep 2020 14:48:59
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).		22 Sep 2020 12:04:03
User entered 'menopause'		01 Sep 2020 04:04:16

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:27:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:25
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered '0.05'	(b) (4), (b) (6)	01 Sep 2020 04:04:16

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:27:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:25
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Sep 2020 04:04:16

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:27:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:25
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:04:16

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:27:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:25
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:04:16

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:27:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:25
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'biweekly'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:04:16

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:27:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:25
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'Transdermal (TRANSDERMAL)'	(b) (4), (b) (6)	01 Sep 2020 04:04:16

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:27:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:25
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:04:16

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:27:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:25
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'un UNK 2014'	(b) (4), (b) (6)	01 Sep 2020 04:04:16

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:25
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:04:16

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:27:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:25
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Gerardo Pena (b) (4)	17 Nov 2020 22:46:45
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	01 Sep 2020 04:04:16

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:27:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:25
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered '12 Nov 2020' reason for change: New Information	(b) (4)	17 Nov 2020 22:46:45
User entered empty.	Gerardo Pena (b) (4)	01 Sep 2020 04:04:16
	(b) (4), (b) (6)	

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:27:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:25
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:04:16

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:27:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:25
User entered empty.	System	01 Sep 2020 04:04:16

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:27:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:25
User entered empty.	System	01 Sep 2020 04:04:16

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:27:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:33:25
User entered empty.	System	01 Sep 2020 04:04:16

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:27:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTI-ACNE PREPARATIONS, ATC: ANTI-ACNE PREPARATIONS FOR TOPICAL USE, ATC: RETINOIDS FOR TOPICAL USE IN ACNE, PRODUCT: TRETINOIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Sep 2020 10:44:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 10:44:55
Data point term sent to Coder	System	23 Sep 2020 14:51:01
Data point term sent to Coder	System	23 Sep 2020 14:49:56
Coding entries removed.	(b) (4), (b) (6)	23 Sep 2020 14:49:35
User entered 'TRETINOIN CREAM 0.05%' reason for change: Data Entry Error		23 Sep 2020 14:49:35
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTI-ACNE PREPARATIONS, ATC: ANTI-ACNE PREPARATIONS FOR TOPICAL USE, ATC: RETINOIDS FOR TOPICAL USE IN ACNE, PRODUCT: TRETINOIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 06:37:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 06:37:48
Data point term sent to Coder	System	01 Sep 2020 04:06:24
User entered 'tretinoin cream'	(b) (4), (b) (6)	01 Sep 2020 04:05:47

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:27:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:05:47

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:27:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'acne'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:05:47

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:27:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User closed query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. Dose = 1; Other Unit, Specify = Application). Review and amend as appropriate. ' (Site from DM). Query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. Dose = 1; Other Unit, Specify = Application). Review and amend as appropriate. ' answered with 'updated' (Site from DM). User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 15:06:57
		23 Sep 2020 14:51:17
		23 Sep 2020 14:50:12
		23 Sep 2020 04:19:41
User opened query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. Dose = 1; Other Unit, Specify = Application). Review and amend as appropriate. ' (Site from DM). User entered '0.05'		01 Sep 2020 04:05:47

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:27:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please review and confirm if (Topical) is the more appropriate route for this medication. Update Con Med eCRF if applicable.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:05:06
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please review and confirm if (Topical) is the more appropriate route for this medication. Update Con Med eCRF if applicable.' answered with 'updated' (Site from DM).		23 Sep 2020 14:51:22
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please review and confirm if (Topical) is the more appropriate route for this medication. Update Con Med eCRF if applicable.' (Site from DM).		23 Sep 2020 04:19:51
User entered 'Other (OTHER)'		01 Sep 2020 04:05:47

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:27:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'application' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 14:50:12
User entered '%'		01 Sep 2020 04:05:47

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:27:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:05:47

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:27:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:05:47

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:27:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'Topical (TOPICAL)' reason for change: Data Entry Error	(b) (4)	23 Sep 2020 14:50:12
User entered 'Other (OTHER)'	(b) (4), (b) (6)	01 Sep 2020 04:05:47

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:27:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 14:50:12
User entered 'application'		01 Sep 2020 04:05:47

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:27:54

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'un UNK 1997'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:05:47

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:05:47

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:27:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:05:47

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:27:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:05:47

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:27:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 04:05:47

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:27:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	01 Sep 2020 04:05:47

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:27:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Sep 2020 04:05:47

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:27:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 04:05:47

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:27:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFECTIVES, ATC: ANTIBIOTICS, PRODUCT: TOBRAMYCIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Mar 2021 08:25:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 08:25:22
Data point term sent to Coder	System	26 Mar 2021 14:54:20
Coding entries removed.	Nathan Cortez (b) (4)	26 Mar 2021 14:54:11
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFECTIVES, ATC: ANTIBIOTICS, PRODUCT: TOBRAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 14:29:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 14:29:58
Data point term sent to Coder	System	25 Feb 2021 20:49:59
User entered 'Tobramycin 0.3%'	Gerardo Pena (b) (4) (b) (4)	25 Feb 2021 20:49:42

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:27:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Feb 2021 20:49:42

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:27:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
	(b) (4)	
User entered 'Conjunctivitis' reason for change: Data Entry Error	Nathan Cortez (b) (4)	26 Mar 2021 14:54:11
	(b) (4)	
User entered 'pink eye'	Gerardo Pena (b) (4)	25 Feb 2021 20:49:42
	(b) (4)	

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:27:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered '2'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Feb 2021 20:49:42

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:27:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'Other (OTHER)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Feb 2021 20:49:42

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:27:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'drops'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Feb 2021 20:49:42

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:27:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'other (OTHER)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Feb 2021 20:49:42

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:27:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'every four hours'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Feb 2021 20:49:42

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:27:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'Other (OTHER)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Feb 2021 20:49:42

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:27:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'ophthalmologic'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Feb 2021 20:49:42

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:27:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered '23 Feb 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Feb 2021 20:49:42

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Feb 2021 20:49:42

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:27:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:31
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	03 May 2021 19:04:03
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Gerardo Pena (b) (4)	03 May 2021 19:04:03
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
	(b) (4)	
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	25 Feb 2021 20:49:42
	(b) (4)	

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:27:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:31
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	03 May 2021 19:04:03
	(b) (4)	
User entered '9 Mar 2021' reason for change: New Information	Gerardo Pena (b) (4)	03 May 2021 19:04:03
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
	(b) (4)	
User entered empty.	Gerardo Pena (b) (4)	25 Feb 2021 20:49:42
	(b) (4)	

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:27:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:48:58
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Feb 2021 20:49:42

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:27:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 20:49:42

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:27:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 20:49:42

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:27:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 20:49:42

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:27:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:31
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ENDOCRINE THERAPY, ATC: HORMONE ANTAGONISTS AND RELATED AGENTS, ATC: AROMATASE INHIBITORS, PRODUCT: ANASTROZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	03 May 2021 19:28:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 19:28:15
Data point term sent to Coder	System	03 May 2021 19:11:01
User entered 'Anastrozole'	Gerardo Pena (b) (4) (b) (4)	03 May 2021 19:10:57

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:27:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:31
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 May 2021 19:10:57

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:27:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:31
User entered 'Invasive Lobular Carcinoma'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 May 2021 19:10:57

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:27:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:31
User entered 'I'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 May 2021 19:10:57

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:27:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:31
User entered 'mg (mg)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 May 2021 19:10:57

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:27:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:31
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 May 2021 19:10:57

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:27:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:31
User entered 'once daily (QD)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 May 2021 19:10:57

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:27:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:31
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 May 2021 19:10:57

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:27:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:31
User entered 'Oral (ORAL)'	(b) (4) Gerardo Pena (b) (4)	03 May 2021 19:10:57

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:27:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:31
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 May 2021 19:10:57

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:27:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:31
User entered '25 Mar 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 May 2021 19:10:57

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:27:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:31
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 May 2021 19:10:57

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:27:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:31
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 May 2021 19:10:57

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:27:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:31
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 May 2021 19:10:57

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:27:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:31
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 May 2021 19:10:57

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:27:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	03 May 2021 19:10:57

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:27:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 19:10:57

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:27:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 May 2021 19:10:57

US3292365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:27:54

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:38
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Yes (Y)'	(b) (4) Antonio Gutierrez (b) (4)	09 Nov 2020 21:57:59

US3292365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:27:54

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '8 Oct 2020'	(b) (4) Antonio Gutierrez (b) (4)	09 Nov 2020 21:58:34

US3292365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:27:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Mammogram'	(b) (4) Antonio Gutierrez (b) (4)	09 Nov 2020 21:58:34

US3292365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:27:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User closed query 'Per DM CLR: Indication = OTHER, however, please confirm if the indication could be recorded as one of the available choice (i.e. Diagnostic). Reconcile and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 14:02:21
Query 'Per DM CLR: Indication = OTHER, however please confirm if the indication could be recorded as one of the available choice (i.e. Diagnostic). Reconcile and update as appropriate, otherwise clarify.' answered with 'updated' (Site from DM).		19 Feb 2021 02:06:21
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error		19 Feb 2021 02:06:11
User opened query 'Per DM CLR: Indication = OTHER, however, please confirm if the indication could be recorded as one of the available choice (i.e. Diagnostic). Reconcile and update as appropriate, otherwise clarify.' (Site from DM).		02 Dec 2020 09:44:46
User entered 'Other (OTHER)'	Antonio Gutierrez (b) (4)	09 Nov 2020 21:58:34

US3292365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:27:54

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	19 Feb 2021 02:06:11
User entered 'Preventative'	Antonio Gutierrez (b) (4)	09 Nov 2020 21:58:34

US3292365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:27:54

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '29 Oct 2020'	(b) (4) Antonio Gutierrez (b) (4)	09 Nov 2020 21:59:11

US3292365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:27:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Mammogram'	(b) (4) Antonio Gutierrez (b) (4)	09 Nov 2020 21:59:11

US3292365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:27:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
	(b) (4)	
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	24 Nov 2020 22:40:15
User entered 'Adverse Event (AE)'	Antonio Gutierrez (b) (4)	09 Nov 2020 21:59:11

US3292365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:27:54

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4) Antonio Gutierrez (b) (4)	09 Nov 2020 21:59:11

US3292365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:27:54

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '3 Nov 2020'	(b) (4) Antonio Gutierrez (b) (4)	09 Nov 2020 21:59:37

US3292365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:27:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Left Breast Biopsy'	(b) (4) Antonio Gutierrez (b) (4)	09 Nov 2020 21:59:37

US3292365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:27:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
	(b) (4)	
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	24 Nov 2020 22:40:29
User entered 'Adverse Event (AE)'	Antonio Gutierrez (b) (4)	09 Nov 2020 21:59:37

US3292365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:27:54

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty.	(b) (4) Antonio Gutierrez (b) (4)	09 Nov 2020 21:59:37

US3292365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:27:54

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:21:50

US3292365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:27:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'Mastectomy'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:21:50

US3292365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:27:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	(b) (4) System	26 Jan 2021 18:22:10
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	26 Jan 2021 18:21:50
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	26 Jan 2021 18:21:50

US3292365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:27:54

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered empty; reason for change New Information	(b) (4), (b) (6)	26 Jan 2021 18:22:10
User entered 'Invasive lobular carcinoma'		26 Jan 2021 18:21:50

US3292365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:27:54

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:31
User entered '5 Apr 2021'	(b) (4) Gerardo Pena (b) (4)	03 May 2021 19:12:39
	(b) (4)	

US3292365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:27:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:31
User entered 'reconstruction breast revision'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 May 2021 19:12:39

US3292365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:27:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:31
User entered 'Adverse Event (AE)'	(b) (4) Gerardo Pena (b) (4)	03 May 2021 19:12:39

US3292365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:27:54

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:31
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 May 2021 19:12:39

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'USA-US072-2020-MRNA-1273-P301000010'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.		10 Nov 2020 23:40:15
User entered 'Yes (Y)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

Death

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'Yes (Y)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'Douglas'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'Denham'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered '7940 Floyd Curl Drive'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'San Antonio'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered '78229'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
Reviewed for Safety.	(b) (4)	24 Nov 2020 17:32:25
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
User entered 'US'	System	10 Nov 2020 23:41:55

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '5'	(b) (4)	19 Feb 2021 16:11:25
User entered '4'	System	27 Jan 2021 19:46:40
User entered '3'	System	25 Nov 2020 20:32:10
User entered '2'	System	24 Nov 2020 17:32:43
User entered '1'	System	10 Nov 2020 23:41:55

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'USA-US072-2020-MRNA-1273-P301000010'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.		10 Nov 2020 23:40:15
User entered 'Yes (Y)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'Yes (Y)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'Douglas'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'Denham'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered '7940 Floyd Curl Drive'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'San Antonio'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered '78229'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
Reviewed for Safety.	(b) (4)	24 Nov 2020 17:32:25
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
User entered 'US'	System	10 Nov 2020 23:41:55

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '5'	(b) (4)	19 Feb 2021 16:11:25
User entered '4'	System	27 Jan 2021 19:46:40
User entered '3'	System	25 Nov 2020 20:32:10
User entered '2'	System	24 Nov 2020 17:32:43
User entered '1'	System	10 Nov 2020 23:41:55

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:27:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:47:26
User entered '10/Nov/2020 18:41'	System	10 Nov 2020 23:41:55

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:27:54

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
Reviewed for Safety.	(b) (4)	24 Nov 2020 17:32:25
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
User entered 'l'		10 Nov 2020 23:41:55

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'USA-US072-2020-MRNA-1273-P301000010'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'Yes (Y)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

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Generated On: 09 Jun 2021 16:27:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.		10 Nov 2020 23:40:15
User entered 'Yes (Y)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'Douglas'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.		10 Nov 2020 23:40:15
User entered 'Denham'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered '7940 Floyd Curl Drive'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'San Antonio'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered '78229'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
Reviewed for Safety.	(b) (4)	24 Nov 2020 17:32:25
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
User entered 'US'	System	10 Nov 2020 23:41:55

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '5'	(b) (4)	19 Feb 2021 16:11:25
User entered '4'	System	27 Jan 2021 19:46:40
User entered '3'	System	25 Nov 2020 20:32:10
User entered '2'	System	24 Nov 2020 17:32:43
User entered '1'	System	10 Nov 2020 23:41:55

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:27:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '24/Nov/2020 12:32'	(b) (4) System	24 Nov 2020 17:32:43

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:27:54

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
Reviewed for Safety.	(b) (4)	25 Nov 2020 20:31:49
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 17:32:43
DataPoint Un-verified.		24 Nov 2020 17:32:43
User entered '1' reason for change: Data Entry Error		24 Nov 2020 17:32:43
Reviewed for Safety.		24 Nov 2020 17:32:25
DataPoint Verified.		23 Nov 2020 19:47:26
User entered '0'		10 Nov 2020 23:41:55

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'USA-US072-2020-MRNA-1273-P301000010'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.		10 Nov 2020 23:40:15
User entered 'Yes (Y)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

Death

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'Yes (Y)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'Douglas'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'Denham'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered '7940 Floyd Curl Drive'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'San Antonio'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered '78229'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
Reviewed for Safety.	(b) (4)	24 Nov 2020 17:32:25
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
User entered 'US'	System	10 Nov 2020 23:41:55

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '5'	(b) (4)	19 Feb 2021 16:11:25
User entered '4'	System	27 Jan 2021 19:46:40
User entered '3'	System	25 Nov 2020 20:32:10
User entered '2'	System	24 Nov 2020 17:32:43
User entered '1'	System	10 Nov 2020 23:41:55

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:27:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '25/Nov/2020 15:32'	(b) (4) System	25 Nov 2020 20:32:10

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:27:54

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
Reviewed for Safety.	(b) (4)	27 Jan 2021 19:46:27
User entered 'I'	(b) (4), (b) (6)	25 Nov 2020 20:32:10

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'USA-US072-2020-MRNA-1273-P301000010'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'Yes (Y)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'Yes (Y)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'Douglas'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'Denham'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered '7940 Floyd Curl Drive'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'San Antonio'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered '78229'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 17:32:25
DataPoint Verified.		23 Nov 2020 19:47:26
User entered 'US'	System	10 Nov 2020 23:41:55

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '5'	(b) (4)	19 Feb 2021 16:11:25
User entered '4'	System	27 Jan 2021 19:46:40
User entered '3'	System	25 Nov 2020 20:32:10
User entered '2'	System	24 Nov 2020 17:32:43
User entered '1'	System	10 Nov 2020 23:41:55

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:27:54

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '27/Jan/2021 14:46'	(b) (4) System	27 Jan 2021 19:46:40

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:27:54

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:11:08
User entered 'I'		27 Jan 2021 19:46:40

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

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[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'USA-US072-2020-MRNA-1273-P301000010'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.		10 Nov 2020 23:40:15
User entered 'Yes (Y)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'Yes (Y)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'Douglas'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'Denham'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered '7940 Floyd Curl Drive'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.		10 Nov 2020 23:40:15
User entered 'San Antonio'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
DataPoint Verified.	(b) (4)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered '78229'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
Reviewed for Safety.	(b) (4)	24 Nov 2020 17:32:25
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
User entered 'US'	System	10 Nov 2020 23:41:55

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '5'	(b) (4)	19 Feb 2021 16:11:25
User entered '4'	System	27 Jan 2021 19:46:40
User entered '3'	System	25 Nov 2020 20:32:10
User entered '2'	System	24 Nov 2020 17:32:43
User entered '1'	System	10 Nov 2020 23:41:55

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:27:54

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered '19/Feb/2021 11:11'	(b) (4) System	19 Feb 2021 16:11:25

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:27:54

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 18:44:21
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:11:25