

US3632075 (Prod: Grady Health System)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:15:35

All time stamps listed in this document are displayed in GMT

US3632075

Form: Participant Creation

Data signed: (b) (4) 05 Apr 2021 01:13:39

Generated On: 10 Jun 2021 09:15:35

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[Participant ID](#)

US3632075

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

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US3632075

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Mar 2021 12:21:41

Generated On: 10 Jun 2021 09:15:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Mar 2021 12:21:41

Generated On: 10 Jun 2021 09:15:35

Date of Birth (MMM yyyy)	(b) (6) 1940
Age	79
Age Units	YEARS
Age (Derived)	79
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Mar 2021 12:21:41

Generated On: 10 Jun 2021 09:15:35

Date of Informed Consent ( <i>dd MMM yyyy</i> )	11 SEP 2020
Month and Year of Informed Consent (derived)	SEP 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) 15 Mar 2021 12:21:41

Generated On: 10 Jun 2021 09:15:35

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Mar 2021 12:21:41

Generated On: 10 Jun 2021 09:15:35

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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) 22 Apr 2021 15:41:26

Generated On: 10 Jun 2021 09:15:35

Condition	CORONARY ARTERY DISEASE (UNRECONSTRUCTABLE)
Start date (dd MMM yyyy)	1 JAN 2004
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 2004
Start Year (derived)	2004
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 22 Apr 2021 15:41:26

Generated On: 10 Jun 2021 09:15:35

Condition	HEART ATTACK
Start date (dd MMM yyyy)	01 JAN 2010
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)	1 JAN 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 22 Apr 2021 15:41:26

Generated On: 10 Jun 2021 09:15:35

Condition	SINUS BRADYCARDIA
Start date (dd MMM yyyy)	1 JAN 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 22 Apr 2021 15:41:26

Generated On: 10 Jun 2021 09:15:35

Condition	ATRIAL FIBRILLATION
Start date (dd MMM yyyy)	1 JAN 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 (5)

Data signed: (b) (4) 22 Apr 2021 15:41:26

Generated On: 10 Jun 2021 09:15:35

Condition	TYPE 2 DIABETES
Start date (dd MMM yyyy)	1 JAN 1989
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 1989
Start Year (derived)	1989
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 22 Apr 2021 15:41:26

Generated On: 10 Jun 2021 09:15:35

Condition	CHARCOT FOOT
Start date (dd MMM yyyy)	1 UNK 2003
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)	1 UNK 2004
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	JAN 2004
Stop Year (derived)	2004

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 22 Apr 2021 15:41:26

Generated On: 10 Jun 2021 09:15:35

Condition	LEFT LEG AMPUTATION
Start date (dd MMM yyyy)	1 UNK 2004
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)	1 UNK 2004
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	JAN 2004
Stop Year (derived)	2004

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 22 Apr 2021 15:41:26

Generated On: 10 Jun 2021 09:15:35

Condition	PERIPHERAL ARTERY PAD
Start date (dd MMM yyyy)	1 UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 22 Apr 2021 15:41:26

Generated On: 10 Jun 2021 09:15:35

Condition	DISTAL ARTERIAL BYPASS
Start date (dd MMM yyyy)	1 JAN 2004
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)	1 JAN 2004
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	JAN 2004
Stop Year (derived)	2004



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 22 Apr 2021 15:41:26

Generated On: 10 Jun 2021 09:15:35

Condition	SEVERE RENAL DISEASE
Start date (dd MMM yyyy)	1 JAN 2001
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 2001
Start Year (derived)	2001
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 22 Apr 2021 15:41:26

Generated On: 10 Jun 2021 09:15:35

Condition	ACUTE RENAL FAILURE
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	1 AUG 2020
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	AUG 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 22 Apr 2021 15:41:26

Generated On: 10 Jun 2021 09:15:35

Condition	HYPERTENSION
Start date (dd MMM yyyy)	1 UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 22 Apr 2021 15:41:26

Generated On: 10 Jun 2021 09:15:35

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	1 JAN 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 22 Apr 2021 15:41:26

Generated On: 10 Jun 2021 09:15:35

Condition	NARROWING OF C5 & C6
Start date (dd MMM yyyy)	1 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 (15)

Data signed: (b) (4) 22 Apr 2021 15:41:26

Generated On: 10 Jun 2021 09:15:35

Condition	CHRONIC SWELLING OF RIGHT LEG
Start date (dd MMM yyyy)	1 JAN 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 (16)

Data signed: (b) (4) 22 Apr 2021 15:41:26

Generated On: 10 Jun 2021 09:15:35

Condition	RIGHT LEG SEPSIS
Start date (dd MMM yyyy)	1 UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 22 Apr 2021 15:41:26

Generated On: 10 Jun 2021 09:15:35

Condition	CATARACT SURGERY ON LEFT EYE
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)	1 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 (18)

Data signed: (b) (4) 22 Apr 2021 15:41:26

Generated On: 10 Jun 2021 09:15:35

Condition	APPENDECTOMY
Start date (dd MMM yyyy)	UN UNK 1945
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)	1 UNK 1945
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1945
Start Year (derived)	1945
Stop Month and Year (derived)	JAN 1945
Stop Year (derived)	1945

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 22 Apr 2021 15:41:26

Generated On: 10 Jun 2021 09:15:35

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 1950
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)	1 UNK 1950
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1950
Start Year (derived)	1950
Stop Month and Year (derived)	JAN 1950
Stop Year (derived)	1950

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 22 Apr 2021 15:41:26

Generated On: 10 Jun 2021 09:15:35

Condition	RIGHT TOE AMPUTATION
Start date (dd MMM yyyy)	UN UNK 1959
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)	1 UNK 1959
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1959
Start Year (derived)	1959
Stop Month and Year (derived)	JAN 1959
Stop Year (derived)	1959

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 22 Apr 2021 15:41:26

Generated On: 10 Jun 2021 09:15:35

Condition	SEVERE ABDOMINAL PAIN
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	1 UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 22 Apr 2021 15:41:26

Generated On: 10 Jun 2021 09:15:35

Condition	BILIARY DYSKINESIA
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	1 UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 22 Apr 2021 15:41:26

Generated On: 10 Jun 2021 09:15:35

Condition	RETROGRADE CANNULATION
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	1 UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 22 Apr 2021 15:41:26

Generated On: 10 Jun 2021 09:15:35

Condition	SPHINCTEROTOMY COMMON BILE DUCT ENTERING THE DUODENUM
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	1 UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (25)

Data signed: (b) (4) 22 Apr 2021 15:41:26

Generated On: 10 Jun 2021 09:15:35

Condition	LAPAROSCOPIC CHOLECYSTECTOMY
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	1 UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013



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Folder: Screening

Form: Medical History (26)

Data signed: (b) (4) 22 Apr 2021 15:41:26

Generated On: 10 Jun 2021 09:15:35

Condition	PANCREATITIS
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	1 UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (27)

Data signed: (b) (4) 22 Apr 2021 15:41:26

Generated On: 10 Jun 2021 09:15:35

Condition	REPAIR OF HERNIA
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	1 UNK 2014
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

US3632075

Folder: Screening

Form: Medical History (28)

Data signed: (b) (4) 22 Apr 2021 15:41:26

Generated On: 10 Jun 2021 09:15:35

Condition	RIGHT LEG LYMPHEDEMA
Start date (dd MMM yyyy)	1 JAN 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 (29)

Data signed: (b) (4) 22 Apr 2021 15:41:26

Generated On: 10 Jun 2021 09:15:35

Condition	FLU SHOT
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	27 SEP 2020
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	SEP 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (30)

Data signed: (b) (4) 22 Apr 2021 15:41:26

Generated On: 10 Jun 2021 09:15:35

Condition	PACEMAKER PLACEMENT
Start date (dd MMM yyyy)	1 JAN 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	1 JAN 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (31)

Data signed: (b) (4) 22 Apr 2021 15:41:26

Generated On: 10 Jun 2021 09:15:35

Condition	VENOUS INSUFFICIENCY IN RIGHT LEG
Start date (dd MMM yyyy)	01 UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (32)

Data signed: (b) (4) 22 Apr 2021 15:41:26

Generated On: 10 Jun 2021 09:15:35

Condition	HEART FAILURE
Start date (dd MMM yyyy)	01 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)	_____

US3632075

Folder: Screening

Form: Medical History (33)

Data signed: (b) (4) 22 Apr 2021 15:41:26

Generated On: 10 Jun 2021 09:15:35

Condition	HERPES ZOSTER
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)	_____



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Folder: Screening

Form: Medical History (34)

Data signed: (b) (4) 22 Apr 2021 15:41:26

Generated On: 10 Jun 2021 09:15:35

Condition	CHRONIC SWELLING OF R LEG
Start date (dd MMM yyyy)	01 JAN 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)	_____

US3632075

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Mar 2021 12:21:41

Generated On: 10 Jun 2021 09:15:35

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	11 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	13:43 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 13:43
Height ( <i>xxx.x</i> )	64.5 in
Weight ( <i>xxx.x</i> )	186 lb
BMI ( <i>xxx.x</i> )	31.49948 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Mar 2021 12:21:41

Generated On: 10 Jun 2021 09:15:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Mar 2021 12:21:41

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

---

**Specify**

---

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

**No Risk Identified** False

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

US3632075

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Mar 2021 12:21:41

Generated On: 10 Jun 2021 09:15:35

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

US3632075

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 08 Mar 2021 14:41:42

Generated On: 10 Jun 2021 09:15:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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	VISIT1

US3632075

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 08 Mar 2021 14:41:42

Generated On: 10 Jun 2021 09:15:35

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

What was the participant's randomization number? 190645

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 ☒

US3632075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 08 Mar 2021 14:41:42

Generated On: 10 Jun 2021 09:15:35

Height	ND - Not Done
Weight	ND - Not Done



US3632075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Mar 2021 14:41:42

Generated On: 10 Jun 2021 09:15:35

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	13:43 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 13:43
Temperature (xxx.x)	96.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3632075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Mar 2021 14:41:42

Generated On: 10 Jun 2021 09:15:35

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	16:49 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 16:49
Temperature (xxx.x)	96.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	151 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3632075

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 08 Mar 2021 14:41:42

Generated On: 10 Jun 2021 09:15:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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

US3632075

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 08 Mar 2021 14:41:42

Generated On: 10 Jun 2021 09:15:35

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 11 SEP 2020

What was the treatment time? (00:00-23:59) 16:18 (24 HR)

Treatment Date and Time (derived) 11 SEP 2020 16:18

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

US3632075

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Mar 2021 14:41:42

Generated On: 10 Jun 2021 09:15:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 SEP 2020
Collection time (00:00-23:59)	15:15 (24 HR)
Collection date and time (derived)	11 SEP 2020 15:15

US3632075

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 08 Mar 2021 14:41:42

Generated On: 10 Jun 2021 09:15:35

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:20	11 SEP 2020 15:20
Nasopharyngeal Swab 2	No		

US3632075

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:41:42

Generated On: 10 Jun 2021 09:15:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

**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

96.7 °F

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

Yes ☐  
No ☒

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

PC Time Stamp 11 SEP 2020 16:56

PC Open Date & Time 11 SEP 2020 16:38

PC Close Date & Time 11 SEP 2020 19:08



US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

**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	11 SEP 2020 21:32
PC Open Date & Time	11 SEP 2020 20:03
PC Close Date & Time	12 SEP 2020 11:59

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:15:35

**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

97.9 °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

12 SEP 2020 20:06

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:15:35

**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

97.6 °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

13 SEP 2020 18:47

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:15:35

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**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

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 20:17

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:15:35

**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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 20:22

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:15:35

**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

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

16 SEP 2020 18:43

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:15:35

**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

97.1 °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

17 SEP 2020 19:43

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 16:58

PC Open Date & Time

11 SEP 2020 16:38

PC Close Date & Time

11 SEP 2020 19:08



US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 21:33

PC Open Date & Time

11 SEP 2020 20:03

PC Close Date & Time

12 SEP 2020 11:59

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 20:08

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 18:47

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 20:17

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 20:31

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 18:43

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 19:44

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

**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 ☐



US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 17:00
PC Open Date & Time	11 SEP 2020 16:38
PC Close Date & Time	11 SEP 2020 19:08

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

**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 ☐

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 21:34
PC Open Date & Time	11 SEP 2020 20:03
PC Close Date & Time	12 SEP 2020 11:59

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:15:35

**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 ☒

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:15:35

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 20:09
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:15:35

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 ☒

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:15:35

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 18:49
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:15:35

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)



US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:15:35

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 20:18
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:15:35

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:15:35

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 20:32
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:15:35

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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Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:15:35

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 18:44
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:15:35

**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 ☒

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:15:35

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 19:44
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3632075

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 14:41:42

Generated On: 10 Jun 2021 09:15:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3632075

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:41:42

Generated On: 10 Jun 2021 09:15:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632075

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 14:41:42

Generated On: 10 Jun 2021 09:15:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3632075

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:41:42

Generated On: 10 Jun 2021 09:15:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632075

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 14:41:42

Generated On: 10 Jun 2021 09:15:35

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 02 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3632075

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:41:42

Generated On: 10 Jun 2021 09:15:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632075

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 08 Mar 2021 14:41:42

Generated On: 10 Jun 2021 09:15:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 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	VISIT2

US3632075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Mar 2021 14:41:42

Generated On: 10 Jun 2021 09:15:35

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)	13 OCT 2020
Time of assessment (00:00-23:59)	14:35 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 14:35
Temperature (xxx.x)	96.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3632075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Mar 2021 14:41:42

Generated On: 10 Jun 2021 09:15:35

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	17:13 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 17:13
Temperature (xxx.x)	96.0 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG



US3632075

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Mar 2021 14:41:42

Generated On: 10 Jun 2021 09:15:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 OCT 2020

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

US3632075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 08 Mar 2021 14:41:42

Generated On: 10 Jun 2021 09:15:35

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) 13 OCT 2020

What was the treatment time? (00:00-23:59) 16:43 (24 HR)

Treatment Date and Time (derived) 13 OCT 2020 16:43

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

US3632075

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Mar 2021 14:41:42

Generated On: 10 Jun 2021 09:15:35

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 OCT 2020

Collection time (00:00-23:59)

15:04 (24 HR)

Collection date and time (derived)

13 OCT 2020 15:04

US3632075

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 08 Mar 2021 14:41:42

Generated On: 10 Jun 2021 09:15:35

Collection date (dd MMM yyyy)			13 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:09	13 OCT 2020 15:09
Nasopharyngeal Swab 2	No		

US3632075

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:41:42

Generated On: 10 Jun 2021 09:15:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

**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

96.0 °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

13 OCT 2020 17:18

PC Open Date & Time

13 OCT 2020 17:03

PC Close Date & Time

13 OCT 2020 19:33

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

**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 96.0 °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	13 OCT 2020 21:25
PC Open Date & Time	13 OCT 2020 20:28
PC Close Date & Time	14 OCT 2020 11:59

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:15:35

**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

14 OCT 2020 23:51

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59



US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:15:35

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**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

96.8 °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

16 OCT 2020 01:49

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:15:35

**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

95.9 °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

16 OCT 2020 20:08

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:15:35

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:15:35

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:15:35

**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.

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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

19 OCT 2020 23:13

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 OCT 2020 17:20

PC Open Date & Time

13 OCT 2020 17:03

PC Close Date & Time

13 OCT 2020 19:33

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

**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)

3

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

13 OCT 2020 21:37

PC Open Date & Time

13 OCT 2020 20:28

PC Close Date & Time

14 OCT 2020 11:59

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 OCT 2020 23:53

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59



US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:15:35

**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

16 OCT 2020 01:50

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:15:35

**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

16 OCT 2020 20:09

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:15:35

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:15:35

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:15:35

**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 ☐

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

3

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

19 OCT 2020 23:25

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

**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 ☐

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

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

No ☒

Yes ☐

PC Time stamp	13 OCT 2020 17:19
PC Open Date & Time	13 OCT 2020 17:03
PC Close Date & Time	13 OCT 2020 19:33

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Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

**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 ☐



US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

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

No ☒

Yes ☐

PC Time stamp	13 OCT 2020 21:39
PC Open Date & Time	13 OCT 2020 20:28
PC Close Date & Time	14 OCT 2020 11:59

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:15:35

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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Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:15:35

Yes <input type="checkbox"/>	
PC Time stamp	14 OCT 2020 23:55
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:15:35

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:15:35

Yes <input type="checkbox"/>	
PC Time stamp	16 OCT 2020 01:51
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:15:35

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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Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:15:35

Yes <input type="checkbox"/>	
PC Time stamp	16 OCT 2020 20:10
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:15:35

**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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Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:15:35

Yes ☐

PC Time stamp

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:15:35

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 ☐

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Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:15:35

Yes ☐

PC Time stamp

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:15:35

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 23:26
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3632075

Folder: Diary Dose 2 (1)

Form: Redness\_Day(8)

Generated On: 10 Jun 2021 09:15:35

TIMEPOINT

DAY 8

Is there any REDNESS AT INJECTION SITE?

Yes ☐

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

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

PC Time Stamp

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3632075

Folder: Diary Dose 2 (1)

Form: Redness\_Day(9)

Generated On: 10 Jun 2021 09:15:35

TIMEPOINT

DAY 9

Is there any REDNESS AT INJECTION SITE?

Yes ☐

No ☒

PC Time Stamp

21 OCT 2020 23:32

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3632075

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 10 Jun 2021 09:15:35

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time Stamp

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59



US3632075

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your

None ☒

**FATIGUE**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 21 OCT 2020 23:32

PC Open Date & Time 21 OCT 2020 12:00

PC Close Date & Time 22 OCT 2020 11:59

US3632075

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:15:35

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3632075

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 09:15:35

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	21 OCT 2020 23:32
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3632075

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 14:41:42

Generated On: 10 Jun 2021 09:15:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3632075

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:41:42

Generated On: 10 Jun 2021 09:15:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632075

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 14:41:42

Generated On: 10 Jun 2021 09:15:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3632075

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:41:42

Generated On: 10 Jun 2021 09:15:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632075

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 14:41:42

Generated On: 10 Jun 2021 09:15:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3632075

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:41:42

Generated On: 10 Jun 2021 09:15:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632075

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 08 Mar 2021 14:41:42

Generated On: 10 Jun 2021 09:15:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 NOV 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

US3632075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Mar 2021 14:41:42

Generated On: 10 Jun 2021 09:15:35

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) \_\_\_\_\_

US3632075

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Mar 2021 14:41:42

Generated On: 10 Jun 2021 09:15:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 NOV 2020

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

US3632075

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Mar 2021 14:41:42

Generated On: 10 Jun 2021 09:15:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 NOV 2020
Collection time (00:00-23:59)	14:12 (24 HR)
Collection date and time (derived)	11 NOV 2020 14:12

US3632075

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:41:42

Generated On: 10 Jun 2021 09:15:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	15 NOV 2020 05:56:57
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3632075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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 <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°F/38°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"/>



**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 13:43:41
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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	29 NOV 2020 23:42:09
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 DEC 2020 09:43:35

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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 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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

13 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

17 DEC 2020 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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 <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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	20 DEC 2020 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 DEC 2020 23:59
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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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 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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	27 DEC 2020 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	31 DEC 2020 23:59
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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**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

04 JAN 2021 23:12:10

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 JAN 2021 10:15:52
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 JAN 2021 14:07:40
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

DAY 138

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

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24 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 JAN 2021 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 FEB 2021 12:36:26

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59



US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

DAY 152

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

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07 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 FEB 2021 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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 <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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

[Patient Cloud Close Date & Time](#)

18 FEB 2021 23:59

US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

21 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

25 FEB 2021 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

DAY 173

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

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28 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 MAR 2021 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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 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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

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07 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAR 2021 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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 <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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

14 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

18 MAR 2021 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 MAR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 MAR 2021 23:59

US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

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28 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 APR 2021 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

04 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 APR 2021 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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 <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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

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11 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 APR 2021 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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 <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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

18 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

22 APR 2021 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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 <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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 APR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 APR 2021 23:59



US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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 <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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

02 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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 <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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

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09 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 MAY 2021 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

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23 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAY 2021 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

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27 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUL 2021 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

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18 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 JUL 2021 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 JUL 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 JUL 2021 23:59
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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

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08 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 AUG 2021 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	15 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 AUG 2021 23:59
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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

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22 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 AUG 2021 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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 <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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

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29 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 SEP 2021 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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

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

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

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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



US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

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26 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 SEP 2021 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 OCT 2021 23:59



US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 NOV 2021 23:59

US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 NOV 2021 23:59

US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

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28 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 DEC 2021 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**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 ☐

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	26 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	30 DEC 2021 23:59
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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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°F/38°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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

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16 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 JAN 2022 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

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23 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 JAN 2022 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**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 ☐

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

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06 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 FEB 2022 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**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 ☐

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**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 ☐

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

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27 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 MAR 2022 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

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06 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAR 2022 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

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

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

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 MAR 2022 23:59

US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

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20 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAR 2022 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**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 ☐

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

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27 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAR 2022 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**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 ☐

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	03 APR 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	07 APR 2022 23:59
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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**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 ☐

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 APR 2022 23:59

US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**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 ☐

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

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24 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 APR 2022 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

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01 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 MAY 2022 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

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08 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 MAY 2022 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

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29 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 JUN 2022 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**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 ☐

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

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05 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 JUN 2022 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

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12 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 JUN 2022 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

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19 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 JUN 2022 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**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 ☐

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

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26 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 JUN 2022 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**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 ☐

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

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31 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 AUG 2022 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	14 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 AUG 2022 23:59
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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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 <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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

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21 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 AUG 2022 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**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 ☐

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

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28 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 SEP 2022 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 SEP 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 SEP 2022 23:59
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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

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09 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 OCT 2022 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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"/>

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 OCT 2022 23:59

US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

30 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

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[Patient Cloud Open Date & Time](#)

06 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

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US3632075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

DAY 796

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3632075**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 NOV 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 NOV 2022 23:59

**US3632075**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 10 Jun 2021 09:15:35**

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

US3632075

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 14:41:42

Generated On: 10 Jun 2021 09:15:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3632075

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:41:42

Generated On: 10 Jun 2021 09:15:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632075

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 01:14:00

Generated On: 10 Jun 2021 09:15:35

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

SAFETY CALL WAS MISSED  
DUE TO OL VISIT

*If Contact Not Made, please provide Comments*

US3632075

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 01:14:00

Generated On: 10 Jun 2021 09:15:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632075

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 01:14:00

Generated On: 10 Jun 2021 09:15:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3632075

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 01:14:00

Generated On: 10 Jun 2021 09:15:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632075

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 01:14:00

Generated On: 10 Jun 2021 09:15:35

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3632075

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 01:14:00

Generated On: 10 Jun 2021 09:15:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3632075**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:35**

Was this visit performed? Yes ☐  
No ☐

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

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

Folder OID \_\_\_\_\_

US3632075

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:35

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

US3632075

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:15:35

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.*

**US3632075**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:15:35**

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date ( <i>dd MMM yyyy</i> )	<hr/>
Collection time ( <i>00:00-23:59</i> )	<hr/>
Collection date and time (derived)	<hr/>

**US3632075**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:35**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag



**US3632075**

**Folder: Covid-19 Assessment (1)**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:15:35**

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"/>

**US3632075**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 10 Jun 2021 09:15:35**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3632075

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

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 01:13:59

Generated On: 10 Jun 2021 09:15:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3632075

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 01:34:57

Generated On: 10 Jun 2021 09:15:35

Date of updated informed consent ( <i>dd MMM yyyy</i> )	4 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	4 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

**US3632075**

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

**Form: Vital Signs - Dosing**

**Data signed: (b) (4) 05 Apr 2021 01:13:59**

**Generated On: 10 Jun 2021 09:15:35**

Height	64.5 in
Weight	192.6 lb
BMI (xxx.x)	32.61720

US3632075

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 01:13:59

Generated On: 10 Jun 2021 09:15:35

Height	64.5 in
Weight	192.6 lb
BMI (xxx.x)	32.61720
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)	4 JAN 2021
Time of assessment (00:00-23:59)	14:27 (24 HR)
Vital Signs Date and Time (derived)	4 JAN 2021 14:27
Temperature (xxx.x)	96 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3632075

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 01:13:59

Generated On: 10 Jun 2021 09:15:35

Height	64.5 in
Weight	192.6 lb
BMI (xxx.x)	32.61720
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)	4 JAN 2021
Time of assessment (00:00-23:59)	16:35 (24 HR)
Vital Signs Date and Time (derived)	4 JAN 2021 16:35
Temperature (xxx.x)	95.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3632075

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

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 01:13:59

Generated On: 10 Jun 2021 09:15:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 JAN 2021

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



US3632075

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

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 01:13:59

Generated On: 10 Jun 2021 09:15:35

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 4 JAN 2021

What was the treatment time? (00:00-23:59) 16:02 (24 HR)

Treatment Date and Time (derived) 4 JAN 2021 16:02

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

US3632075

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 01:13:59

Generated On: 10 Jun 2021 09:15:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 JAN 2021
Collection time (00:00-23:59)	14:45 (24 HR)
Collection date and time (derived)	4 JAN 2021 14:45

US3632075

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Apr 2021 01:13:59

Generated On: 10 Jun 2021 09:15:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 JAN 2021
Collection time (00:00 - 23:59)	14:48
Collection Date and Time (derived)	4 JAN 2021 14:48

US3632075

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

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 01:13:59

Generated On: 10 Jun 2021 09:15:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632075

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 01:14:00

Generated On: 10 Jun 2021 09:15:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3632075

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 01:14:00

Generated On: 10 Jun 2021 09:15:35

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

US3632075

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 01:13:59

Generated On: 10 Jun 2021 09:15:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3632075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 01:13:59

Generated On: 10 Jun 2021 09:15:35

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)	4 FEB 2021
Time of assessment (00:00-23:59)	10:11 (24 HR)
Vital Signs Date and Time (derived)	4 FEB 2021 10:11
Temperature (xxx.x)	96.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG



US3632075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 01:13:59

Generated On: 10 Jun 2021 09:15:35

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)	4 FEB 2021
Time of assessment (00:00-23:59)	12:38 (24 HR)
Vital Signs Date and Time (derived)	4 FEB 2021 12:38
Temperature (xxx.x)	96.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3632075

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 01:13:39

Generated On: 10 Jun 2021 09:15:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 FEB 2021

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

US3632075

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 01:13:39

Generated On: 10 Jun 2021 09:15:35

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 4 FEB 2021

What was the treatment time? (00:00-23:59) 12:05 (24 HR)

Treatment Date and Time (derived) 4 FEB 2021 12:05

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

US3632075

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 01:13:39

Generated On: 10 Jun 2021 09:15:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632075

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 01:14:00

Generated On: 10 Jun 2021 09:15:35

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3632075

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 01:14:00

Generated On: 10 Jun 2021 09:15:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632075

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 01:13:59

Generated On: 10 Jun 2021 09:15:35

Was this visit performed? Yes ☐  
No ☒

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

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

Folder OID OLD57

US3632075

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 01:13:59

Generated On: 10 Jun 2021 09:15:35

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) \_\_\_\_\_



US3632075

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 01:13:59

Generated On: 10 Jun 2021 09:15:35

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.*

US3632075

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 01:13:59

Generated On: 10 Jun 2021 09:15:35

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

**US3632075**

**Folder: Unscheduled (2)**

**Form: Unscheduled Visit Assessment**

**Generated On: 10 Jun 2021 09:15:35**

Visit Date	
<b>Please check all assessments that apply for this visit</b>	
Physical Exam	
Vital Signs	
Immunogenicity Assessment	
Pregnancy Test	

US3632075

Folder: Unscheduled 10 Nov 2020

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 05 Apr 2021 01:14:00

Generated On: 10 Jun 2021 09:15:35

Visit Date	10 NOV 2020
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	False
Immunogenicity Assessment	False
Pregnancy Test	False

US3632075

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Mar 2021 12:26:16

Generated On: 10 Jun 2021 09:15:35

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3632075

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

AEID	
Adverse event	DIARRHEA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	15 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	16 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

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 type="radio"/> Related <input checked="" 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)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3632075

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

AEID	
Adverse event	WORSENING OF LYMPHEDEMA OF LEG
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)	29 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product 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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PATIENT WENT TO CARDIOLOGIST FOR WORSENING OF LYMPHEDEMA OF LEG AND HIS DOSAGE OF LASIX WAS INCREASED TO 40 MG. THIS IS UPDATED IN CON-MEDS

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Data signed: (b) (4) 28 Apr 2021 22:19:03**

**Generated On: 10 Jun 2021 09:15:35**

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

AEID	USA-US120-2021-MRNA-1273-P30 1000004
Adverse event	MYOCARDIAL INFARCTION
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)	12 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)	03 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	12 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	03 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

Number of Days in ICU	
Persistent or significant disability or incapacity	True
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 Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

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PARTICIPANT WAS ADMITTED  
TO HOSPITAL (EMORY  
CLIFTON) VIA EMS ON 2/12 FOR  
MYOCARDIAL INFARCTION.  
UNDERWENT RIGHT HEART  
CARDIAC CATHETERIZATION.  
TROPONIN DOWNTRENDED, NO  
FURTHER CARDIAC  
INTERVENTION WAS GIVEN  
FOR MI

---

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

AEID	USA-US120-2021-MRNA-1273-P30 1000004
Adverse event	WORSENING RENAL FAILURE
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)	14 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)	03 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	12 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	03 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product 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 type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	ACUTE RENAL FAILURE IMPROVED, NOW WITH NEW BASELINE RENAL FUNCTION
Narrative	AKI ON CKD, SUSPECTED DUE TO CARDIORENAL SYNDROME FROM MI. NO DIALYSIS PERFORMED, WAS DISCHARGED ON ORAL DIURETICS

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Data signed: (b) (4) 28 Apr 2021 22:19:03**

**Generated On: 10 Jun 2021 09:15:35**

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

AEID	USA-US120-2021-MRNA-1273-P30 1000004
Adverse event	WORSENING HEART FAILURE
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)	12 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)	03 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input 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	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	12 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	03 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	NEW BASELINE EF OF 15% (WAS PREVIOUSLY HIGHER PER RECORDS)
Narrative	SEQUELAE OF HOSPITALIZATION DUE TO MI. ECHO WITH NEW BASELINE EF OF 15%.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Data signed: (b) (4) 28 Apr 2021 22:19:03**

**Generated On: 10 Jun 2021 09:15:35**

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

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0

US3632075

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

AEID

Adverse event

CYSTITIS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

12 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	OCCURRED DURING HOSPITALIZATION. URINE CULTURE WAS NOT SENT DUE TO NEGATIVE URINALYSIS BUT WAS TREATED EMPIRICALLY WITH ANTIBIOTICS
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Data signed: (b) (4) 28 Apr 2021 22:19:03**

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

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US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Apr 2021 01:13:39

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

Yes ☒

No ☐

---

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

---

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

Name of Medication N-ACETYL-CYSTEINE

Prophylaxis Yes ☐  
No ☒

Indication TYPE 2 DIABETES

Dose per administration 600

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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US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

	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)	1 UNK 2001	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

Name of Medication GRAPE SEED EXTRACT

Prophylaxis Yes ☐  
No ☒

Indication TYPE 2 DIABETES

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

	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)	1 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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication MI PREVENTION

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

	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)	1 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 (4)

Data signed: (b) (4) 28 Apr 2021 22:19:03

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Name of Medication COUMADIN

Prophylaxis Yes ☐  
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

2.5 MG MONDAY, TUESDAY,  
THURSDAY, AND FRIDAY

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) 28 Apr 2021 22:19:03

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	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)	03 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 22:19:03

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Name of Medication CARVEDILOL

Prophylaxis Yes ☐  
No ☒

Indication CORONARY ARTERY DISEASE

Dose per administration 6.25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 22:19:03

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	1 UNK	2015
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 22:19:03

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Name of Medication ISOSORBIDE

Prophylaxis Yes ☐  
No ☒

Indication CORONARY ARTERY DISEASE

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 (6)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

	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)	1 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) _____		
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 (7)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

Name of Medication GENUUIA

Prophylaxis Yes ☐  
No ☒

Indication TYPE 2 DIABETES

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 22:19:03

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Name of Medication VITAMIN D

Prophylaxis Yes ☒  
No ☐

Indication GENERAL SUPPLEMENT

Dose per administration 5000

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

	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)	1 UNK 2018	
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) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

Name of Medication UBIQUINOL

Prophylaxis Yes ☐  
No ☒

Indication CORONARY ARTERY DISEASE

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) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

	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)	1 UNK 2018	
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)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

Name of Medication D-RIBOSE

Prophylaxis Yes ☐  
No ☒

Indication CORONARY ARTERY DISEASE

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

	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)	1 UNK 2017	
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 (11)

Data signed: (b) (4) 28 Apr 2021 22:19:03

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Name of Medication CARNITINE

Prophylaxis Yes ☐  
No ☒

Indication CORONARY ARTERY DISEASE

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 (11)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

	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)	1 UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

Name of Medication LASIX

Prophylaxis Yes ☐  
No ☒

Indication LEFT LEG AMPUTATION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

2-3 TIMES A WEEK

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

	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)	1 UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

Name of Medication LIPITOR

Prophylaxis Yes ☐  
No ☒

Indication CORONARY ARTERY DISEASE

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

	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)	1 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 (14)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

Name of Medication MONTELUKAST

Prophylaxis Yes ☐  
No ☒

Indication SEVERE RENAL DISEASE

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 (14)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

	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)	1 UNK 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 (15)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

Name of Medication METRONIDAZOLE

Prophylaxis Yes ☐  
No ☒

Indication DIARRHEA

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 (15)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

	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)		15 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

Name of Medication	FLU SHOT
Prophylaxis	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Indication	SEASONAL FLU SHOT
------------	-------------------

Dose per administration	UNKNOWN
-------------------------	---------

Dose unit	mg <input type="radio"/>
	ug <input type="radio"/>
	mL <input type="radio"/>
	g <input type="radio"/>
	IU <input type="radio"/>
	tablet <input type="radio"/>
	capsule <input type="radio"/>
	puff <input type="radio"/>
	Other <input checked="" type="radio"/>

If dose unit is Other, specify	UNKNOWN
--------------------------------	---------

Frequency	once daily <input type="radio"/>
	twice daily <input type="radio"/>
	three times daily <input type="radio"/>
	four times daily <input type="radio"/>
	every other day <input type="radio"/>
	every week <input type="radio"/>
	every month <input type="radio"/>
	as needed <input type="radio"/>
	once <input checked="" type="radio"/>
	unknown <input type="radio"/>
	other <input type="radio"/>

If frequency is Other, specify	
--------------------------------	--

Route of administration	Oral <input type="radio"/>
	Topical <input type="radio"/>
	Subcutaneous <input type="radio"/>
	Transdermal <input type="radio"/>
	Intraocular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		27 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		27 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

Name of Medication METRONIDAZOLE

Prophylaxis Yes ☐  
No ☒

Indication DIARRHEA ( AE)

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 (17)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

	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)		23 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

Name of Medication CEFTRIAXONE

Prophylaxis Yes ☐  
No ☒

Indication CYSTITIS

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

	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 checked="" 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)	13 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)	19 FEB 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

Name of Medication MILRINONE

Prophylaxis Yes ☐  
No ☒

Indication WORSENING HEART FAILURE

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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 CONTINUOUS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		17 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

Name of Medication ASPIRIN

Prophylaxis Yes ☐  
No ☒

Indication MYOCARDIAL INFARCTION

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐  
No ☒

Indication MYOCARDIAL INFARCTION

Dose per administration 80

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 (21)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

Name of Medication SODIUM BICARBONATE

Prophylaxis Yes ☐  
No ☒

Indication WORSENING RENAL FAILURE

Dose per administration 1350

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 (22)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

	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)		14 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		3
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 (23)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

Name of Medication CARVEDILOL

Prophylaxis Yes ☐  
No ☒

Indication MYOCARDIAL INFARCTION

Dose per administration 6.25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

	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)	14 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	23 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 28 Apr 2021 22:19:03

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Name of Medication CARVEDILOL

Prophylaxis Yes ☐  
No ☒

Indication MYOCARDIAL INFARCTION

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

	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)		23 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 28 Apr 2021 22:19:03

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Name of Medication MAGNESIUM SULFATE

Prophylaxis Yes ☐  
No ☒

Indication MYOCARDIAL INFARCTION

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	14 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 28 Apr 2021 22:19:03

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Name of Medication	HEPARIN
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	MYOCARDIAL INFARCTION
Dose per administration	UNKNOWN
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	UNKNOWN
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input checked="" type="radio"/>
If frequency is Other, specify	CONTINUOUS DRIP (FREQUENT TITRATION)
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 28 Apr 2021 22:19:03

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	Intraocular	<input type="radio"/>
	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 checked="" type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	13 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)		22 FEB 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐  
No ☒

Indication WORSENING RENAL FAILURE

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

	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)	14 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	22 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

Name of Medication TORSEMIDE

Prophylaxis Yes ☐  
No ☒

Indication WORSENING RENAL FAILURE

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 (29)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

	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)		27 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 28 Apr 2021 22:19:03

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Name of Medication ISORDIL

Prophylaxis Yes ☐  
No ☒

Indication WORSENING HEART FAILURE  
(AE)

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

	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)		03 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

Name of Medication HYDRALAZINE

Prophylaxis Yes ☐  
No ☒

Indication WORSENING HEART FAILURE  
(AE)

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

	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)		03 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

Name of Medication PATIROMER

Prophylaxis Yes ☐  
No ☒

Indication WORSENING RENAL FAILURE  
(AE)

Dose per administration 16.8

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

	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)		03 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

Name of Medication ACYCLOVIR

Prophylaxis Yes ☐  
No ☒

Indication HERPES ZOSTER

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

	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)		01 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

Name of Medication LASIX

Prophylaxis Yes ☐  
No ☒

Indication LEFT LEG AMPUTATION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

	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)		29 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

Name of Medication COUMADIN

Prophylaxis Yes ☐  
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

WEDNESDAYS, SATURDAYS,  
AND SUNDAYS

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

	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)	03 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3632075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Apr 2021 01:13:39

Generated On: 10 Jun 2021 09:15:35

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3632075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 05 Apr 2021 01:13:39

Generated On: 10 Jun 2021 09:15:35

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
12 FEB 2021	PORTABLE CHEST XRAY- 1 VIEW	Adverse Event	
13 FEB 2021	CT CHEST WITHOUT CONTRAST	Adverse Event	
13 FEB 2021	CT ABDOMEN AND PELVIS WITHOUT IV CONTRAST	Adverse Event	
12 FEB 2021	12 LEAD EKG	Adverse Event	
13 FEB 2021	12-LEAD EKG	Adverse Event	
14 FEB 2021	TRANSTHORACIC ECHOCARDIOGRAM	Adverse Event	
17 FEB 2021	RIGHT HEART CATHETERIZATION	Adverse Event	
23 FEB 2021	TRANSTHORACIC ECHOCARDIOGRAM	Adverse Event	

US3632075

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:15:35

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: 10 Jun 2021 09:15:35

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 ☐

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

SAEID	USA-US120-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input 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	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

SAEID	USA-US120-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input 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	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	23/FEB/2021 16:42
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

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

SAEID	USA-US120-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input 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	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	25/FEB/2021 13:19
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

SAEID	USA-US120-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input 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	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	16/MAR/2021 08:25
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

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

SAEID	USA-US120-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input 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	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	19/MAR/2021 09:02
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

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

SAEID	USA-US120-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input 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	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	22/MAR/2021 06:28
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form (6)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

SAEID	USA-US120-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input 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	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	29/MAR/2021 11:29
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form (7)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

SAEID	USA-US120-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input 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	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	30/MAR/2021 11:47
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form (8)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

SAEID	USA-US120-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input 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	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	06/APR/2021 09:48
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form (9)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

SAEID	USA-US120-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input 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	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	21/APR/2021 08:56
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

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form (10)

Data signed: (b) (4) 28 Apr 2021 22:19:03

Generated On: 10 Jun 2021 09:15:35

SAEID	USA-US120-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input 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	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	23/APR/2021 10:43
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3632075 (Prod: Grady Health System)

**US3632075**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:15:35**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 22:00:54
User entered 'US3632075'	RWS_ENDPOINT	11 Sep 2020 17:04:45
	ENDPOINT (b) (4)	

**US3632075**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:35**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:03:06
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	11 Sep 2020 19:42:04

US3632075

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:15:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 16:03:06
User entered '11 SEP 2020'	RWS_ENDPOINT	11 Sep 2020 17:04:46
	ENDPOINT (b) (4)	



**US3632075**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:03:06
User entered 'Clinic (Clinic)'	Sarah Wiatrek (b) (4)	11 Sep 2020 19:42:04

**US3632075**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:35**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'SCRN'	System	11 Sep 2020 19:42:04

**US3632075**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 16:03:37
User entered (b) (6) 1940'	RWS_ENDPOINT	11 Sep 2020 17:04:47
	ENDPOINT (b) (4)	

**US3632075**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:15:35**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:03:37
User entered '79'	Sarah Wiatrek (b) (4)	11 Sep 2020 19:42:17

**US3632075**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:15:35**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'YEARS'	System	11 Sep 2020 19:42:17

**US3632075**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:15:35**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '79'	System	11 Sep 2020 19:42:40

**US3632075**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:15:35**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:03:37
User entered 'Male (M)'	Sarah Wiatrek (b) (4)	11 Sep 2020 19:42:17

US3632075

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:15:35

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:03:37
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Sarah Wiatrek (b) (4)	11 Sep 2020 19:42:17



**US3632075**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:15:35**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:03:37
User entered 'I'	Sarah Wiatrek (b) (4)	11 Sep 2020 19:42:17

**US3632075**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:15:35**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:03:37
User entered '0'	Sarah Wiatrek (b) (4)	11 Sep 2020 19:42:17

**US3632075**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:15:35**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:03:37
User entered '0'	Sarah Wiatrek (b) (4)	11 Sep 2020 19:42:17

**US3632075**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:15:35**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:03:37
User entered '0'	Sarah Wiatrek (b) (4)	11 Sep 2020 19:42:17

**US3632075**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:15:35**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:03:37
User entered '0'	Sarah Wiatrek (b) (4)	11 Sep 2020 19:42:17

**US3632075**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:15:35**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:03:37
User entered '0'	Sarah Wiatrek (b) (4)	11 Sep 2020 19:42:17

**US3632075**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:15:35**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:03:37
User entered empty.	Sarah Wiatrek (b) (4)	11 Sep 2020 19:42:17

**US3632075**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:15:35**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:03:37
User entered '0'	Sarah Wiatrek (b) (4)	11 Sep 2020 19:42:17



**US3632075**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:15:35**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:03:37
User entered '0'	Sarah Wiatrek (b) (4)	11 Sep 2020 19:42:17

US3632075

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:15:35

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:10:12
User entered '11 Sep 2020'	Sarah Wiatrek (b) (4)	11 Sep 2020 19:42:40

**US3632075**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Sep 2020'	System	11 Sep 2020 19:42:40

**US3632075**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '2020'	System	11 Sep 2020 19:42:40

US3632075

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:15:35

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:10:12
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 19:42:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 19:42:49
User entered 'Amendment 3 (3)' reason for change: Data Entry Error	Sarah Wiatrek (b) (4)	11 Sep 2020 19:42:49
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 19:42:40
User entered empty.	Sarah Wiatrek (b) (4)	11 Sep 2020 19:42:40

US3632075

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:15:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:10:12
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	11 Sep 2020 19:42:40

**US3632075**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:10:12
User entered empty.	Sarah Wiatrek (b) (4)	11 Sep 2020 19:42:40

**US3632075**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:15:35**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:10:12
User entered empty.	Sarah Wiatrek (b) (4)	11 Sep 2020 19:42:40



**US3632075**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:15:35**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:10:12
User entered 'No (N)'	Sarah Wiatrek (b) (4)	11 Sep 2020 19:42:40

**US3632075**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:15:35**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 16:10:12
User entered empty.	RWS_ENDPOINT	11 Sep 2020 17:04:46
	ENDPOINT (b) (4)	

**US3632075**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:15:35**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'I'	System	11 Sep 2020 19:43:02

US3632075

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:15:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:23:30
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
User entered 'Yes (Y)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	11 Sep 2020 19:43:02

**US3632075**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 10 Jun 2021 09:15:35**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:10:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 18:29:48

US3632075

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:15:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 16:30:40
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 00:25:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 00:25:56
Data point term sent to Coder	System	14 Sep 2020 18:54:33
User entered 'Coronary Artery Disease (unreconstructable)'	(b) (4), (b) (6)	14 Sep 2020 18:53:58

US3632075

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:15:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 16:46:20
User closed query 'The source notes the start year as 2004; please verify and update.' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 16:46:17
Query 'The source notes the start year as 2004; please verify and update.' answered with 'Updated' (Site from CRA).	(b) (4), (b) (6)	11 Jan 2021 18:17:00
DataPoint Un-verified.	(b) (4), (b) (6)	11 Jan 2021 18:16:39
User entered '1 Jan 2004' reason for change: New Information	(b) (4), (b) (6)	11 Jan 2021 18:16:39
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 16:31:00
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:30:52
User opened query 'The source notes the start year as 2004; please verify and update.' (Site from CRA).	(b) (4), (b) (6)	08 Jan 2021 16:30:28
User entered '1 Jan 2005' reason for change: New Information	Christina Bacher (b) (4)	13 Oct 2020 19:53:31
User entered '1 Jan 2010'	(b) (4), (b) (6)	14 Sep 2020 18:53:58

**US3632075**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:30:52
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:53:58



**US3632075**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:30:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 18:53:58

**US3632075**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:30:52
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 18:53:58

**US3632075**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:30:52
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:53:58

**US3632075**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 2004'	System	11 Jan 2021 18:16:39
User entered 'Jan 2005'	System	13 Oct 2020 19:53:31
User entered 'Jan 2010'	System	14 Sep 2020 18:53:58

**US3632075**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '2004'	System	11 Jan 2021 18:16:39
User entered '2005'	System	13 Oct 2020 19:53:31
User entered '2010'	System	14 Sep 2020 18:53:58

**US3632075**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	14 Sep 2020 18:53:58

**US3632075**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	14 Sep 2020 18:53:58

US3632075

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:15:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:31:31
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Heart attack - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 18:55:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 18:55:50
Data point term sent to Coder	System	14 Sep 2020 18:54:33
User entered 'Heart Attack'	(b) (4), (b) (6)	14 Sep 2020 18:54:12



**US3632075**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:34:03
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Un-verified.	(b) (4) Sarah Wiatrek (b) (4)	05 Feb 2021 16:11:24
User entered '01 Jan 2010' reason for change: Data Entry Error	(b) (4) Sarah Wiatrek (b) (4)	05 Feb 2021 16:11:24
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:31:31
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 18:54:12

US3632075

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:15:35

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:34:06
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
User closed query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	(b) (4)	05 Feb 2021 16:12:48
DataPoint Un-verified.	Sarah Wiatrek (b) (4)	05 Feb 2021 16:12:48
User entered '0' reason for change: Data Entry Error	(b) (4)	05 Feb 2021 16:12:48
User opened query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	Sarah Wiatrek (b) (4)	05 Feb 2021 16:12:48
DataPoint Verified.	(b) (4)	05 Feb 2021 16:11:24
User entered '1'	(b) (4), (b) (6)	08 Jan 2021 16:31:31
	(b) (4), (b) (6)	14 Sep 2020 18:54:12

**US3632075**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:31:31
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 18:54:12

**US3632075**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:31:31
User entered '1 Jan 2010'	(b) (4), (b) (6)	14 Sep 2020 18:54:12

**US3632075**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:31:31
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:54:12

**US3632075**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 2010'	System	05 Feb 2021 16:11:24
User entered empty.	System	14 Sep 2020 18:54:12

**US3632075**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '2010'	System	05 Feb 2021 16:11:24
User entered empty.	System	14 Sep 2020 18:54:12

**US3632075**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 2010'	System	14 Sep 2020 18:54:12



**US3632075**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '2010'	System	14 Sep 2020 18:54:12

US3632075

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:15:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:45:43
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Sinus bradycardia, LLT: Sinus bradycardia - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 15:03:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 15:03:41
Data point term sent to Coder	System	27 Oct 2020 15:02:37
User entered 'SINUS BRADYCARDIA' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 15:01:37
User closed query 'Per MM, please review and update the term to final diagnosis. (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 08:31:54
Data point term sent to Coder	System	13 Oct 2020 19:58:44
Query 'Per MM, please review and update the term to final diagnosis. answered with 'UPDATED' (Site from DM).	Christina Bacher (b) (4)	13 Oct 2020 19:58:29
Coding entries removed.	Christina Bacher (b) (4)	13 Oct 2020 19:58:23
User entered 'Sinus Bradycardia- PACE MAKER' reason for change: Data Entry Error	Christina Bacher (b) (4)	13 Oct 2020 19:58:23
User opened query 'Per MM, please review and update the term to final diagnosis. (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 13:32:49
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac device therapeutic procedures, PT: Cardiac pacemaker insertion, LLT: Cardiac pacemaker insertion - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 18:55:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 18:55:50
Data point term sent to Coder	System	14 Sep 2020 18:54:34
User entered 'Pace Maker'	(b) (4), (b) (6)	14 Sep 2020 18:54:27

US3632075

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:15:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:45:43
User entered '1 Jan 2013' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 15:01:37
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 18:54:27

US3632075

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:15:35

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:45:43
User closed query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 10:03:25
Query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 15:02:01
User closed query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	System	27 Oct 2020 15:01:50
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 15:01:50
User opened query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	System	27 Oct 2020 15:01:37
User opened query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 08:04:45
User entered '1'	(b) (4), (b) (6)	14 Sep 2020 18:54:27

US3632075

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:15:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:45:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 15:01:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 18:54:27

US3632075

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:15:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:45:43
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 15:01:37
User entered '1 Jan 2013'	(b) (4), (b) (6)	14 Sep 2020 18:54:27

**US3632075**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:45:43
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:54:27

**US3632075**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 2013'	System	27 Oct 2020 15:01:37
User entered empty.	System	14 Sep 2020 18:54:27



**US3632075**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '2013'	System	27 Oct 2020 15:01:37
User entered empty.	System	14 Sep 2020 18:54:27

**US3632075**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	27 Oct 2020 15:01:37
User entered 'Jan 2013'	System	14 Sep 2020 18:54:27

**US3632075**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	27 Oct 2020 15:01:37
User entered '2013'	System	14 Sep 2020 18:54:27

US3632075

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:15:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:48:59
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 18:57:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 18:57:01
Data point term sent to Coder	System	14 Sep 2020 18:55:35
User entered 'Atrial Fibrillation'	(b) (4), (b) (6)	14 Sep 2020 18:55:06

**US3632075**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:48:59
User entered '1 Jan 2015'	(b) (4), (b) (6)	14 Sep 2020 18:55:06

**US3632075**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:48:59
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:55:06

**US3632075**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:15:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:48:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 18:55:06

**US3632075**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:48:59
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 18:55:06



**US3632075**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:48:59
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:55:06

**US3632075**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 2015'	System	14 Sep 2020 18:55:06

**US3632075**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '2015'	System	14 Sep 2020 18:55:06

**US3632075**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	14 Sep 2020 18:55:06

**US3632075**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	14 Sep 2020 18:55:06

US3632075

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:15:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 16:49:18
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 18:57:00
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 18:57:00
	(b) (4)	
Data point term sent to Coder	System	14 Sep 2020 18:55:35
User entered 'Type 2 Diabetes'	(b) (4), (b) (6)	14 Sep 2020 18:55:20

**US3632075**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:49:18
User entered '1 Jan 1989'	(b) (4), (b) (6)	14 Sep 2020 18:55:20

**US3632075**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:49:18
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:55:20



**US3632075**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:15:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:49:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 18:55:20

**US3632075**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:49:18
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 18:55:20

**US3632075**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 16:49:18
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:55:20

**US3632075**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 1989'	System	14 Sep 2020 18:55:20

**US3632075**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '1989'	System	14 Sep 2020 18:55:20

**US3632075**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	14 Sep 2020 18:55:20

**US3632075**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	14 Sep 2020 18:55:20

US3632075

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:15:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 17:00:16
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Neuropathic arthropathy, LLT: Charcot arthropathy - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 18:57:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 18:57:50
Data point term sent to Coder	System	14 Sep 2020 18:56:36
User entered 'Charcot Foot'	(b) (4), (b) (6)	14 Sep 2020 18:55:36



**US3632075**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:00:16
User entered '1 UNK 2003'	(b) (4), (b) (6)	14 Sep 2020 18:55:36

**US3632075**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:00:16
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:55:36

**US3632075**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:15:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:00:16
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 18:55:36

**US3632075**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:00:16
User entered '1 UNK 2004'	(b) (4), (b) (6)	14 Sep 2020 18:55:36

**US3632075**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:00:16
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:55:36

**US3632075**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 2003'	System	14 Sep 2020 18:55:36

**US3632075**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '2003'	System	14 Sep 2020 18:55:36

**US3632075**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 2004'	System	14 Sep 2020 18:55:36



**US3632075**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '2004'	System	14 Sep 2020 18:55:36

US3632075

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:15:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 17:06:59
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Limb therapeutic procedures, PT: Leg amputation, LLT: Leg amputation - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 18:57:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 18:57:49
Data point term sent to Coder	System	14 Sep 2020 18:56:37
User entered 'Left Leg Amputation'	(b) (4), (b) (6)	14 Sep 2020 18:55:50

**US3632075**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:06:59
User entered '1 UNK 2004'	(b) (4), (b) (6)	14 Sep 2020 18:55:50

**US3632075**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:06:59
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:55:50

**US3632075**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:15:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:06:59
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 18:55:50

**US3632075**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:06:59
User entered '1 UNK 2004'	(b) (4), (b) (6)	14 Sep 2020 18:55:50

**US3632075**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:06:59
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:55:50

**US3632075**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 2004'	System	14 Sep 2020 18:55:50



**US3632075**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '2004'	System	14 Sep 2020 18:55:50

**US3632075**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 2004'	System	14 Sep 2020 18:55:50

**US3632075**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '2004'	System	14 Sep 2020 18:55:50

US3632075

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:15:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 17:07:06
User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Peripheral vasoconstriction, necrosis and vascular insufficiency, PT: Peripheral arterial occlusive disease, LLT: Peripheral arterial disease - version MedDRA\23.0.	Coder Import (b) (4)	25 Nov 2020 07:04:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	25 Nov 2020 07:04:11
Data point term sent to Coder	System	14 Sep 2020 18:56:36
User entered 'Peripheral Artery PAD'	(b) (4), (b) (6)	14 Sep 2020 18:56:03

**US3632075**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:07:06
User entered '1 UNK 1990'	(b) (4), (b) (6)	14 Sep 2020 18:56:03

**US3632075**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:07:06
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:56:03

**US3632075**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:15:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:07:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 18:56:03

**US3632075**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:07:06
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 18:56:03



**US3632075**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:07:06
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:56:03

**US3632075**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 1990'	System	14 Sep 2020 18:56:03

**US3632075**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '1990'	System	14 Sep 2020 18:56:03

**US3632075**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	14 Sep 2020 18:56:03

**US3632075**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	14 Sep 2020 18:56:03

US3632075

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:15:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User closed query 'Per MM, please include the underlying condition that led to the procedure. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 08:22:54
Query 'Per MM, please include the underlying condition that led to the procedure. ' answered with 'Please see MH #1' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 14:28:03
User opened query 'Per MM, please include the underlying condition that led to the procedure. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 16:08:59
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:06:09
User closed query 'Per MM, please clarify the MH term. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 18:55:25
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Arterial bypass operation, LLT: Arterial bypass operation - version MedDRA\\23.0.	Coder Import (b) (4)	11 Oct 2020 11:14:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Oct 2020 11:14:19
Data point term sent to Coder	System	09 Oct 2020 14:05:04
Query 'Per MM, please clarify the MH term. ' answered with 'Clarified term' (Site from DM).	Isaac Perez (b) (4)	09 Oct 2020 14:05:02
Coding entries removed.	Isaac Perez (b) (4)	09 Oct 2020 14:04:44
User entered 'DISTAL ARTERIAL BYPASS' reason for change: Data Entry Error	Isaac Perez (b) (4)	09 Oct 2020 14:04:44
User opened query 'Per MM, please clarify the MH term. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 13:33:52
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Vascular therapeutic procedures NEC, PT: Vascular graft, LLT: Bypass surgery - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 10:34:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 10:34:40

**US3632075**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:15:35**

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	14 Sep 2020 18:56:37
User entered 'Dystal Bypass'	(b) (4), (b) (6)	14 Sep 2020 18:56:32

US3632075

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:15:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:35:04
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Un-verified.	Sarah Wiatrek (b) (4)	05 Feb 2021 16:12:22
User entered '1 Jan 2004' reason for change: Data Entry Error	Sarah Wiatrek (b) (4)	05 Feb 2021 16:12:22
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '1 Aug 2004' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 15:06:27
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 18:56:32



US3632075

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:15:35

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:06:13
User closed query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 10:04:00
User closed query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	System	27 Oct 2020 15:06:38
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 15:06:38
Query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 15:06:34
User opened query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	System	27 Oct 2020 15:06:27
User opened query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 08:01:30
User entered '1'	(b) (4), (b) (6)	14 Sep 2020 18:56:32

**US3632075**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:15:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:06:16
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 18:56:32

US3632075

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:15:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 16:47:36
User closed query 'The source notes this 01/2004; please verify and update for start and end dates.' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 16:47:34
Query 'The source notes this 01/2004; please verify and update for start and end dates.' answered with 'corrected' (Site from CRA).	Sarah Wiatrek (b) (4)	05 Feb 2021 16:12:31
DataPoint Un-verified.	(b) (4)	05 Feb 2021 16:12:22
User entered '1 Jan 2004' reason for change: Data Entry Error	Sarah Wiatrek (b) (4)	05 Feb 2021 16:12:22
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User opened query 'The source notes this 01/2004; please verify and update for start and end dates.' (Site from CRA).	(b) (4), (b) (6)	08 Jan 2021 17:06:03
User entered '1 Aug 2004' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 15:06:27
User entered '1 Jan 2004'	(b) (4), (b) (6)	14 Sep 2020 18:56:32

**US3632075**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:06:19
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:56:32

**US3632075**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 2004'	System	05 Feb 2021 16:12:22
User entered 'Aug 2004'	System	27 Oct 2020 15:06:27
User entered empty.	System	14 Sep 2020 18:56:32

**US3632075**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '2004'	System	27 Oct 2020 15:06:27
User entered empty.	System	14 Sep 2020 18:56:32

**US3632075**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 2004'	System	05 Feb 2021 16:12:22
User entered 'Aug 2004'	System	27 Oct 2020 15:06:27
User entered 'Jan 2004'	System	14 Sep 2020 18:56:32

**US3632075**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '2004'	System	14 Sep 2020 18:56:32



US3632075

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:15:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4)	08 Jan 2021 17:07:20
User coded data point as SOC: Renal and urinary disorders, HLGT: Nephropathies, HLT: Nephropathies and tubular disorders NEC, PT: Nephropathy, LLT: Renal disease - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 05:35:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 05:35:41
Data point term sent to Coder	System	14 Sep 2020 18:57:38
User entered 'Severe Renal Disease'	(b) (4), (b) (6)	14 Sep 2020 18:56:57

**US3632075**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:07:20
User entered '1 Jan 2001'	(b) (4), (b) (6)	14 Sep 2020 18:56:57

**US3632075**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:07:20
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:56:57

**US3632075**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:15:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:07:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 18:56:57

**US3632075**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:07:20
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 18:56:57

**US3632075**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:07:20
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:56:57

**US3632075**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 2001'	System	14 Sep 2020 18:56:57

**US3632075**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '2001'	System	14 Sep 2020 18:56:57



**US3632075**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	14 Sep 2020 18:56:57

US3632075

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:15:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	14 Sep 2020 18:56:57

US3632075

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:15:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 17:09:08
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Acute kidney injury, LLT: Acute renal failure - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 18:58:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 18:58:45
Data point term sent to Coder	System	14 Sep 2020 18:57:38
User entered 'Acute Renal Failure'	(b) (4), (b) (6)	14 Sep 2020 18:57:16

**US3632075**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:09:08
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 18:57:16

**US3632075**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:09:08
User entered 'I'	(b) (4), (b) (6)	14 Sep 2020 18:57:16

**US3632075**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:15:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:09:08
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 18:57:16

**US3632075**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:09:08
User entered '1 Aug 2020'	(b) (4), (b) (6)	14 Sep 2020 18:57:16

**US3632075**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:09:08
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:57:16



**US3632075**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	14 Sep 2020 18:57:16

**US3632075**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	14 Sep 2020 18:57:16

**US3632075**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Aug 2020'	System	14 Sep 2020 18:57:16

**US3632075**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '2020'	System	14 Sep 2020 18:57:16

US3632075

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:15:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 18:58:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 18:58:45
Data point term sent to Coder	System	14 Sep 2020 18:57:38
User entered 'Hypertension'	(b) (4), (b) (6)	14 Sep 2020 18:57:32

**US3632075**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '1 UNK 2000'	(b) (4), (b) (6)	14 Sep 2020 18:57:32

**US3632075**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:57:32

**US3632075**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:15:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 18:57:32



**US3632075**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 18:57:32

**US3632075**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:57:32

**US3632075**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 2000'	System	14 Sep 2020 18:57:32

**US3632075**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '2000'	System	14 Sep 2020 18:57:32

**US3632075**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	14 Sep 2020 18:57:32

**US3632075**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	14 Sep 2020 18:57:32

US3632075

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:15:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:24:30
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	30 Mar 2021 16:43:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Mar 2021 16:43:03
Data point term sent to Coder	System	30 Mar 2021 16:42:21
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 16:41:46
Coding entries removed.	(b) (4), (b) (6)	30 Mar 2021 16:41:46
Signature has been broken.	(b) (4), (b) (6)	30 Mar 2021 16:41:46
User entered 'HYPERLIPIDEMIA' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 16:41:46
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipemia - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 06:37:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 06:37:36
Data point term sent to Coder	System	14 Sep 2020 18:58:39
User entered 'Hyperlypemia'	(b) (4), (b) (6)	14 Sep 2020 18:57:50

**US3632075**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '1 Jan 2000'	(b) (4), (b) (6)	14 Sep 2020 18:57:50



**US3632075**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:57:50

**US3632075**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:15:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 18:57:50

**US3632075**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 18:57:50

**US3632075**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:57:50

**US3632075**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 2000'	System	14 Sep 2020 18:57:50

**US3632075**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '2000'	System	14 Sep 2020 18:57:50

**US3632075**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	14 Sep 2020 18:57:50

**US3632075**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	14 Sep 2020 18:57:50



US3632075

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:15:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Spine and neck deformities, PT: Cervical spinal stenosis, LLT: Spinal stenosis cervical - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 05:20:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 05:20:14
Data point term sent to Coder	System	14 Sep 2020 18:58:41
User entered 'Narrowing of C5 & C6'	(b) (4), (b) (6)	14 Sep 2020 18:58:11

**US3632075**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '1 UNK 2010'	(b) (4), (b) (6)	14 Sep 2020 18:58:11

**US3632075**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:58:11

**US3632075**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:15:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 18:58:11

**US3632075**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 18:58:11

**US3632075**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:58:11

**US3632075**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 2010'	System	14 Sep 2020 18:58:11

**US3632075**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '2010'	System	14 Sep 2020 18:58:11



**US3632075**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	14 Sep 2020 18:58:11

**US3632075**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	14 Sep 2020 18:58:11

US3632075

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:15:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: General signs and symptoms NEC, PT: Peripheral swelling, LLT: Swelling of legs - version MedDRA\23.0.	Coder Import (b) (4)	15 Sep 2020 00:21:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	15 Sep 2020 00:21:53
Data point term sent to Coder	System	14 Sep 2020 18:58:42
User entered 'Chronic Swelling of Right Leg'	(b) (4), (b) (6)	14 Sep 2020 18:58:34

**US3632075**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '1 Jan 2005'	(b) (4), (b) (6)	14 Sep 2020 18:58:34

**US3632075**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:58:34

**US3632075**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:15:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 18:58:34

**US3632075**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 18:58:34

**US3632075**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:58:34



**US3632075**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 2005'	System	14 Sep 2020 18:58:34

**US3632075**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '2005'	System	14 Sep 2020 18:58:34

**US3632075**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	14 Sep 2020 18:58:34

**US3632075**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	14 Sep 2020 18:58:34

US3632075

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:15:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 16:49:35
User closed query 'Please consider adding location (source notes right leg).' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 16:49:32
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Infections NEC, PT: Localised infection, LLT: Leg infection - version MedDRA\23.0.	Coder Import (b) (4)	12 Jan 2021 17:15:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	12 Jan 2021 17:15:55
Data point term sent to Coder	System	11 Jan 2021 18:25:16
Query 'Please consider adding location (source notes right leg).' answered with 'Updated' (Site from CRA).	(b) (4), (b) (6)	11 Jan 2021 18:24:45
Coding entries removed.	(b) (4), (b) (6)	11 Jan 2021 18:24:39
User entered 'Right Leg SEPSIS' reason for change: Per Query Resolution	(b) (4), (b) (6)	11 Jan 2021 18:24:39
User opened query 'Please consider adding location (source notes right leg).' (Site from CRA).	(b) (4), (b) (6)	08 Jan 2021 17:19:00
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 17:17:50
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Sepsis, bacteraemia, viraemia and fungaemia NEC, PT: Sepsis, LLT: Sepsis - version MedDRA\23.0.	Coder Import (b) (4)	01 Dec 2020 18:26:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	01 Dec 2020 18:26:49
Data point term sent to Coder	System	01 Dec 2020 18:25:49
User closed query 'CDM-Coding: For coding purpose, Please split the term to two terms and record separately as; 1)SEPSIS 2)LYMPHEDEMA 3)VENOUS INSUFFICIENCY' (Site from System).	System	01 Dec 2020 18:25:47

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Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:15:35

Condition

Audit	User	Time (GMT)
Query 'CDM-Coding: For coding purpose,Please split the term to two terms and record separately as; 1)SEPSIS 2)LYMPHEDEMA 3)VENOUS INSUFFICIENCY' answered with 'corrected' (Site from System).	(b) (4), (b) (6)	01 Dec 2020 18:25:47
User entered 'SEPSIS' reason for change: Per Query Resolution	(b) (4), (b) (6)	01 Dec 2020 18:25:34
User opened query 'CDM-Coding: For coding purpose,Please split the term to two terms and record separately as; 1)SEPSIS 2)LYMPHEDEMA 3)VENOUS INSUFFICIENCY' (Site from System).	Coder Import (b) (4) (b) (4)	24 Nov 2020 01:35:01
User closed query 'Per MM, please clarify the MH term ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 08:32:53
Data point term sent to Coder	System	13 Oct 2020 20:01:56
Query 'Per MM, please clarify the MH term ' answered with 'updated' (Site from DM).	Christina Bacher (b) (4) (b) (4)	13 Oct 2020 20:01:31
Coding entries removed.	Christina Bacher (b) (4) (b) (4)	13 Oct 2020 20:01:26
User entered 'Sepsis caused by lymphedema and venous insufficiency' reason for change: Per Query Resolution	Christina Bacher (b) (4) (b) (4)	13 Oct 2020 20:01:26
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Infections NEC, PT: Localised infection, LLT: Leg infection - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 23:26:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 23:26:10
User opened query 'Per MM, please clarify the MH term ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 13:34:29
Data point term sent to Coder	System	29 Sep 2020 18:08:52
User closed query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	System	29 Sep 2020 18:08:35
Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' answered with 'Separated septic episodes and LYMPHEDEMA ' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 18:08:35
Data point term sent to Coder	System	29 Sep 2020 18:07:47

US3632075

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:15:35

Condition

Audit	User	Time (GMT)
User entered '4 SEPTIC EPISODES IN RIGHT LEG' reason for change: Per Query Resolution	(b) (4), (b) (6)	29 Sep 2020 18:07:02
User opened query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	Coder Import (b) (4)	28 Sep 2020 19:42:36
Data point term sent to Coder	System	25 Sep 2020 21:49:48
User closed query 'CDM-Coding: Please clarify this clinical event with more details if it is 1. Septic arthritis or 2. Septic encephalopathyOr Something else and amend /update the term accordingly in the diagnosis field to enable coding. ' (Site from System).	System	25 Sep 2020 21:49:04
Query 'CDM-Coding: Please clarify this clinical event with more details if it is 1. Septic arthritis or 2. Septic encephalopathyOr Something else and amend /update the term accordingly in the diagnosis field to enable coding. ' answered with 'due to chronic lymphedema and chronic skin cellulitis ' (Site from System).	Catherine Abrams (b) (4)	25 Sep 2020 21:49:04
User entered '4 SEPTIC EPISODES IN RIGHT LEG due to chronic lymphedema and chronic skin cellulitis' reason for change: New Information	Catherine Abrams (b) (4)	25 Sep 2020 21:48:59
Data point term sent to Coder	System	24 Sep 2020 18:58:24
User entered '4 SEPTIC EPISODES IN RIGHT LEG' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 18:58:08
User opened query 'CDM-Coding: Please clarify this clinical event with more details if it is 1. Septic arthritis or 2. Septic encephalopathyOr Something else and amend /update the term accordingly in the diagnosis field to enable coding. ' (Site from System).	Coder Import (b) (4)	21 Sep 2020 05:10:35
Data point term sent to Coder	System	14 Sep 2020 18:59:43
User entered '4 Septic Episodes in Right Left'	(b) (4), (b) (6)	14 Sep 2020 18:58:54

US3632075

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:15:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '1 UNK 2017' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Dec 2020 18:25:34
User entered '1 UNK 2015'	(b) (4), (b) (6)	14 Sep 2020 18:58:54



**US3632075**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:58:54

**US3632075**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:15:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 18:58:54

**US3632075**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 18:58:54

**US3632075**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:58:54

**US3632075**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 2017'	System	01 Dec 2020 18:25:34
User entered 'Jan 2015'	System	14 Sep 2020 18:58:54

**US3632075**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '2017'	System	01 Dec 2020 18:25:34
User entered '2015'	System	14 Sep 2020 18:58:54

**US3632075**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	14 Sep 2020 18:58:54

**US3632075**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	14 Sep 2020 18:58:54



US3632075

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:15:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Cataract operation - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 19:00:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 19:00:49
	(b) (4)	
Data point term sent to Coder	System	14 Sep 2020 18:59:44
User entered 'Cataract Surgery on Left Eye'	(b) (4), (b) (6)	14 Sep 2020 18:59:18

**US3632075**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:38:51
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Un-verified.	Sarah Wiatrek (b) (4)	05 Feb 2021 16:15:50
User entered 'UN UNK 2017' reason for change:	Sarah Wiatrek (b) (4)	05 Feb 2021 16:15:50
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 18:59:18

US3632075

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:15:35

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:38:53
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Un-verified.	(b) (4) Sarah Wiatrek (b) (4)	05 Feb 2021 16:15:50
User entered '0' reason for change: Data Entry Error	(b) (4) Sarah Wiatrek (b) (4)	05 Feb 2021 16:15:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '1'	(b) (4), (b) (6)	14 Sep 2020 18:59:18

**US3632075**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:15:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 18:59:18

**US3632075**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '1 UNK 2017'	(b) (4), (b) (6)	14 Sep 2020 18:59:18

**US3632075**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:59:18

**US3632075**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 2017'	System	05 Feb 2021 16:15:50
User entered empty.	System	14 Sep 2020 18:59:18

**US3632075**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '2017'	System	05 Feb 2021 16:15:50
User entered empty.	System	14 Sep 2020 18:59:18



**US3632075**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 2017'	System	14 Sep 2020 18:59:18

**US3632075**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '2017'	System	14 Sep 2020 18:59:18

US3632075

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:15:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendicectomy, LLT: Appendectomy - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 19:00:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 19:00:49
Data point term sent to Coder	System	14 Sep 2020 18:59:46
User entered 'Appendectomy'	(b) (4), (b) (6)	14 Sep 2020 18:59:35

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Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:15:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:39:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Un-verified.	(b) (4) Sarah Wiatrek (b) (4)	05 Feb 2021 16:16:10
User entered 'UN UNK 1945' reason for change:	(b) (4) Sarah Wiatrek (b) (4)	05 Feb 2021 16:16:10
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 18:59:35

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Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:15:35

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:39:12
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Un-verified.	(b) (4) Sarah Wiatrek (b) (4)	05 Feb 2021 16:16:10
User entered '0' reason for change: Data Entry Error	(b) (4) Sarah Wiatrek (b) (4)	05 Feb 2021 16:16:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '1'	(b) (4), (b) (6)	14 Sep 2020 18:59:35

**US3632075**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:15:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 18:59:35

**US3632075**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '1 UNK 1945'	(b) (4), (b) (6)	14 Sep 2020 18:59:35

**US3632075**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:59:35



**US3632075**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 1945'	System	05 Feb 2021 16:16:10
User entered empty.	System	14 Sep 2020 18:59:35

**US3632075**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '1945'	System	05 Feb 2021 16:16:10
User entered empty.	System	14 Sep 2020 18:59:35

**US3632075**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 1945'	System	14 Sep 2020 18:59:35

**US3632075**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '1945'	System	14 Sep 2020 18:59:35

US3632075

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:15:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 19:01:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 19:01:46
Data point term sent to Coder	System	14 Sep 2020 19:00:47
User entered 'Tonsillectomy'	(b) (4), (b) (6)	14 Sep 2020 18:59:48

**US3632075**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:39:26
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Un-verified.	Sarah Wiatrek (b) (4)	05 Feb 2021 16:16:30
User entered 'UN UNK 1950' reason for change:	Sarah Wiatrek (b) (4)	05 Feb 2021 16:16:30
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 18:59:48

US3632075

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:15:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:39:28
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Un-verified.	(b) (4) Sarah Wiatrek (b) (4)	05 Feb 2021 16:16:30
User entered '0' reason for change: Data Entry Error	(b) (4) Sarah Wiatrek (b) (4)	05 Feb 2021 16:16:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '1'	(b) (4), (b) (6)	14 Sep 2020 18:59:48

**US3632075**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:15:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 18:59:48



**US3632075**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '1 UNK 1950'	(b) (4), (b) (6)	14 Sep 2020 18:59:48

**US3632075**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:59:48

**US3632075**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 1950'	System	05 Feb 2021 16:16:30
User entered empty.	System	14 Sep 2020 18:59:48

**US3632075**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '1950'	System	05 Feb 2021 16:16:30
User entered empty.	System	14 Sep 2020 18:59:48

**US3632075**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 1950'	System	14 Sep 2020 18:59:48

**US3632075**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '1950'	System	14 Sep 2020 18:59:48

US3632075

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:15:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4)	08 Jan 2021 17:16:21
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Limb therapeutic procedures, PT: Toe amputation, LLT: Toe amputation - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 05:49:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 05:49:38
Data point term sent to Coder	System	14 Sep 2020 19:00:47
User entered 'Right Toe Amputation'	(b) (4), (b) (6)	14 Sep 2020 19:00:00

US3632075

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:15:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:39:35
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Un-verified.	(b) (4) Sarah Wiatrek (b) (4)	05 Feb 2021 16:17:08
User entered 'UN UNK 1959' reason for change:	(b) (4) Sarah Wiatrek (b) (4)	05 Feb 2021 16:17:08
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 19:00:00



US3632075

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:15:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:39:39
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Un-verified.	(b) (4) Sarah Wiatrek (b) (4)	05 Feb 2021 16:17:08
User entered '0' reason for change: Data Entry Error	(b) (4) Sarah Wiatrek (b) (4)	05 Feb 2021 16:17:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '1'	(b) (4), (b) (6)	14 Sep 2020 19:00:00

**US3632075**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:15:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 19:00:00

**US3632075**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '1 UNK 1959'	(b) (4), (b) (6)	14 Sep 2020 19:00:00

**US3632075**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 19:00:00

**US3632075**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 1959'	System	05 Feb 2021 16:17:08
User entered empty.	System	14 Sep 2020 19:00:00

**US3632075**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '1959'	System	05 Feb 2021 16:17:08
User entered empty.	System	14 Sep 2020 19:00:00

**US3632075**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 1959'	System	14 Sep 2020 19:00:00

**US3632075**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '1959'	System	14 Sep 2020 19:00:00



US3632075

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:15:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain, LLT: Abdominal pain - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 05:35:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 05:35:41
Data point term sent to Coder	System	14 Sep 2020 19:00:47
User entered 'Severe Abdominal Pain'	(b) (4), (b) (6)	14 Sep 2020 19:00:17

US3632075

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:15:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:39:49
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Un-verified.	(b) (4) Sarah Wiatrek (b) (4)	05 Feb 2021 16:17:28
User entered 'UN UNK 2013' reason for change:	(b) (4) Sarah Wiatrek (b) (4)	05 Feb 2021 16:17:28
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 19:00:17

US3632075

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:15:35

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:39:52
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Un-verified.	(b) (4) Sarah Wiatrek (b) (4)	05 Feb 2021 16:17:28
User entered '0' reason for change: Data Entry Error	(b) (4) Sarah Wiatrek (b) (4)	05 Feb 2021 16:17:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '1'	(b) (4), (b) (6)	14 Sep 2020 19:00:17

**US3632075**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:15:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 19:00:17

**US3632075**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '1 UNK 2013'	(b) (4), (b) (6)	14 Sep 2020 19:00:17

**US3632075**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 19:00:17

**US3632075**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 2013'	System	05 Feb 2021 16:17:28
User entered empty.	System	14 Sep 2020 19:00:17

**US3632075**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '2013'	System	05 Feb 2021 16:17:28
User entered empty.	System	14 Sep 2020 19:00:17



**US3632075**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 2013'	System	14 Sep 2020 19:00:17

**US3632075**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '2013'	System	14 Sep 2020 19:00:17

US3632075

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:15:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Gallbladder disorders NEC, PT: Biliary dyskinesia, LLT: Biliary dyskinesia - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 19:02:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 19:02:51
Data point term sent to Coder	System	14 Sep 2020 19:01:49
User entered 'Biliary Dyskinesia'	(b) (4), (b) (6)	14 Sep 2020 19:00:54

**US3632075**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 19:00:54

**US3632075**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered 'I'	(b) (4), (b) (6)	14 Sep 2020 19:00:54

**US3632075**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:15:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 19:00:54

**US3632075**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '1 UNK 2013'	(b) (4), (b) (6)	14 Sep 2020 19:00:54

**US3632075**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 19:00:54



**US3632075**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	14 Sep 2020 19:00:54

**US3632075**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	14 Sep 2020 19:00:54

**US3632075**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 2013'	System	14 Sep 2020 19:00:54

**US3632075**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '2013'	System	14 Sep 2020 19:00:54

US3632075

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:15:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4)	08 Jan 2021 17:16:21
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Catheter placement, LLT: Cannula placement - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 12:28:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 12:28:57
Data point term sent to Coder	System	14 Sep 2020 19:01:48
User entered 'Retrograde Cannulation'	(b) (4), (b) (6)	14 Sep 2020 19:01:22

**US3632075**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 19:01:22

**US3632075**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered 'l'	(b) (4), (b) (6)	14 Sep 2020 19:01:22

**US3632075**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:15:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 19:01:22



**US3632075**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '1 UNK 2013'	(b) (4), (b) (6)	14 Sep 2020 19:01:22

**US3632075**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 19:01:22

**US3632075**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	14 Sep 2020 19:01:22

**US3632075**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	14 Sep 2020 19:01:22

**US3632075**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 2013'	System	14 Sep 2020 19:01:22

**US3632075**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '2013'	System	14 Sep 2020 19:01:22

US3632075

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:15:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:16:21
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Pancreatic therapeutic procedures, PT: Biliary sphincterotomy, LLT: Biliary sphincterotomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 13:31:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 13:31:48
Data point term sent to Coder	System	25 Sep 2020 21:45:41
User closed query 'CDM-Coding: Please enter the location for SPHINCTEROTOMY in order that the term may be coded accurately and to the appropriate site. Please make your changes to the reported term accordingly in the diagnosis field to enable coding. ' (Site from System).	System	25 Sep 2020 21:45:03
Query 'CDM-Coding: Please enter the location for SPHINCTEROTOMY in order that the term may be coded accurately and to the appropriate site. Please make your changes to the reported term accordingly in the diagnosis field to enable coding. ' answered with 'bile duct entering the duodenum ' (Site from System).	Catherine Abrams (b) (4) (b) (4)	25 Sep 2020 21:45:03
User entered 'SPHINCTEROTOMY common bile duct entering the duodenum' reason for change: New Information	Catherine Abrams (b) (4) (b) (4)	25 Sep 2020 21:44:44
User opened query 'CDM-Coding: Please enter the location for SPHINCTEROTOMY in order that the term may be coded accurately and to the appropriate site. Please make your changes to the reported term accordingly in the diagnosis field to enable coding. ' (Site from System).	Coder Import (b) (4) (b) (4)	16 Sep 2020 11:56:33
Data point term sent to Coder	System	14 Sep 2020 19:01:51
User entered 'Sphincterotomy'	(b) (4), (b) (6)	14 Sep 2020 19:01:50

**US3632075**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 19:01:50



**US3632075**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered 'I'	(b) (4), (b) (6)	14 Sep 2020 19:01:50

**US3632075**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:15:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 19:01:50

**US3632075**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '1 UNK 2013'	(b) (4), (b) (6)	14 Sep 2020 19:01:50

**US3632075**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 19:01:50

**US3632075**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	14 Sep 2020 19:01:50

**US3632075**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	14 Sep 2020 19:01:50

**US3632075**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 2013'	System	14 Sep 2020 19:01:50

**US3632075**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '2013'	System	14 Sep 2020 19:01:50



US3632075

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:15:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4)	08 Jan 2021 17:16:21
User coded data point as SOC: Surgical and medical procedures, HLG: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 19:03:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 19:03:48
Data point term sent to Coder	System	14 Sep 2020 19:02:52
User entered 'Laparoscopic Cholecystectomy'	(b) (4), (b) (6)	14 Sep 2020 19:02:18

**US3632075**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 19:02:18

**US3632075**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered 'I'	(b) (4), (b) (6)	14 Sep 2020 19:02:18

**US3632075**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 09:15:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 19:02:18

**US3632075**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '1 UNK 2013'	(b) (4), (b) (6)	14 Sep 2020 19:02:18

**US3632075**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 19:02:18

**US3632075**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	14 Sep 2020 19:02:18

**US3632075**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	14 Sep 2020 19:02:18



**US3632075**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 2013'	System	14 Sep 2020 19:02:18

**US3632075**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '2013'	System	14 Sep 2020 19:02:18

US3632075

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:15:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User coded data point as SOC: Gastrointestinal disorders, HLGT: Exocrine pancreas conditions, HLT: Acute and chronic pancreatitis, PT: Pancreatitis, LLT: Pancreatitis - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 14:06:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 14:06:37
Data point term sent to Coder	System	16 Sep 2020 14:05:44
User entered 'Pancreatitis' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 14:05:40
Data point term sent to Coder	System	14 Sep 2020 19:02:53
User entered 'Panchrotitis'	(b) (4), (b) (6)	14 Sep 2020 19:02:44

**US3632075**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 19:02:44

**US3632075**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered 'I'	(b) (4), (b) (6)	14 Sep 2020 19:02:44

**US3632075**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 09:15:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 19:02:44

**US3632075**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '1 UNK 2013'	(b) (4), (b) (6)	14 Sep 2020 19:02:44

**US3632075**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 19:02:44



**US3632075**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	14 Sep 2020 19:02:44

**US3632075**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	14 Sep 2020 19:02:44

**US3632075**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 2013'	System	14 Sep 2020 19:02:44

**US3632075**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '2013'	System	14 Sep 2020 19:02:44

US3632075

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:15:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Hernia repair, LLT: Hernia repair - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 05:53:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 05:53:44
Data point term sent to Coder	System	14 Sep 2020 19:03:55
User entered 'Repair of Hernia'	(b) (4), (b) (6)	14 Sep 2020 19:03:27

**US3632075**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 19:03:27

**US3632075**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered 'I'	(b) (4), (b) (6)	14 Sep 2020 19:03:27

**US3632075**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 09:15:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 19:03:27



**US3632075**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '1 UNK 2014'	(b) (4), (b) (6)	14 Sep 2020 19:03:27

**US3632075**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 19:03:27

**US3632075**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	14 Sep 2020 19:03:27

**US3632075**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	14 Sep 2020 19:03:27

**US3632075**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 2014'	System	14 Sep 2020 19:03:27

**US3632075**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '2014'	System	14 Sep 2020 19:03:27

US3632075

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:15:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User coded data point as SOC: Vascular disorders, HLGT: Lymphatic vessel disorders, HLT: Lymphoedemas, PT: Lymphoedema, LLT: Lymphedema - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 14:35:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 14:35:48
User closed query 'Per DM CLR: Please specify the location of LYMPHEDEMA. 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)	28 Oct 2020 10:04:28
Data point term sent to Coder	System	27 Oct 2020 15:03:38
Query 'Per DM CLR: Please specify the location of LYMPHEDEMA. 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)	27 Oct 2020 15:03:02
Coding entries removed.	(b) (4), (b) (6)	27 Oct 2020 15:02:57
User entered 'Right leg LYMPHEDEMA' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 15:02:57
User opened query 'Per DM CLR: Please specify the location of LYMPHEDEMA. 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)	27 Oct 2020 08:10:16
User coded data point as SOC: Vascular disorders, HLGT: Lymphatic vessel disorders, HLT: Lymphoedemas, PT: Lymphoedema, LLT: Lymphedema - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 18:08:39

US3632075

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:15:35

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	29 Sep 2020 18:08:39
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	29 Sep 2020 18:07:48
User entered 'LYMPHEDEMA'	(b) (4), (b) (6)	29 Sep 2020 18:07:33



**US3632075**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '1 Jan 2015'	(b) (4), (b) (6)	29 Sep 2020 18:07:33

**US3632075**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 18:07:33

**US3632075**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 09:15:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 18:07:33

**US3632075**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 18:07:33

**US3632075**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 18:07:33

**US3632075**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 2015'	System	29 Sep 2020 18:07:33

**US3632075**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '2015'	System	29 Sep 2020 18:07:33

**US3632075**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	29 Sep 2020 18:07:33



**US3632075**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	29 Sep 2020 18:07:33

US3632075

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 09:15:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:13:12
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 17:22:14
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User closed query 'Per DM CLR Re-Query: Response noted, however, clarify what has been updated, as 'FLU SHOT'; has not been updated in Con Med eCRF page. Please update appropriately or clarify. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 17:39:32
Query 'Per DM CLR Re-Query: Response noted, however, clarify what has been updated, as 'FLU SHOT'; has not been updated in Con Med eCRF page. Please update appropriately or clarify. ' answered with 'Added to Con Med eCRF' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 15:01:53
User opened query 'Per DM CLR Re-Query: Response noted, however, clarify what has been updated, as 'FLU SHOT'; has not been updated in Con Med eCRF page. Please update appropriately or clarify. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 16:36:03
User closed query 'Per DM CLR: Please review and confirm if this should be moved in the Con Med eCRF page. Please update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 16:36:03
Query 'Per DM CLR: Please review and confirm if this should be moved in the Con Med eCRF page. Please update as appropriate. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 15:07:11
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Immunisations, PT: Influenza immunisation, LLT: Influenza immunization - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 12:05:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 12:05:36

US3632075

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 09:15:35

[Condition](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review and confirm if this should be moved in the Con Med eCRF page.Please update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 08:10:52
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Immunisations, PT: Influenza immunisation, LLT: Flu vaccination - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 18:11:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 18:11:41
Data point term sent to Coder	System	29 Sep 2020 18:10:57
User entered 'Flu Shot'	(b) (4), (b) (6)	29 Sep 2020 18:10:02

**US3632075**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:13:12
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 17:22:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 18:10:02

US3632075

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 09:15:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:13:12
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 17:22:18
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered 'I'	(b) (4), (b) (6)	29 Sep 2020 18:10:02

**US3632075**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 09:15:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:13:12
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 18:10:02

**US3632075**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:13:12
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 17:22:21
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '27 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 18:10:02

US3632075

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 09:15:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:13:12
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 17:22:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 18:10:02



**US3632075**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	29 Sep 2020 18:10:02

**US3632075**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	29 Sep 2020 18:10:02

**US3632075**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Sep 2020'	System	29 Sep 2020 18:10:02

**US3632075**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '2020'	System	29 Sep 2020 18:10:02

US3632075

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 09:15:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User closed query 'Per MM, please review and update the term to final diagnosis. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 08:40:44
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac device therapeutic procedures, PT: Cardiac pacemaker insertion, LLT: Cardiac pacemaker insertion - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 18:21:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 18:21:48
Data point term sent to Coder	System	01 Dec 2020 18:20:45
Query 'Per MM, please review and update the term to final diagnosis. ' answered with 'extensive cardiac history including unresectable CAD, MI, afib, HTN, HLD' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 18:20:34
Coding entries removed.	(b) (4), (b) (6)	01 Dec 2020 18:20:30
User entered 'PACEMAKER PLACEMENT' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Dec 2020 18:20:30
User opened query 'Per MM, please review and update the term to final diagnosis. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 17:49:38
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac device therapeutic procedures, PT: Cardiac pacemaker insertion, LLT: Cardiac pacemaker insertion - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 15:06:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 15:06:47
Data point term sent to Coder	System	27 Oct 2020 15:05:44
User entered 'Pace maker placement'	(b) (4), (b) (6)	27 Oct 2020 15:05:11

**US3632075**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '1 Jan 2013'	(b) (4), (b) (6)	27 Oct 2020 15:05:11

**US3632075**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 15:05:11

**US3632075**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 09:15:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 15:05:11



**US3632075**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '1 Jan 2013'	(b) (4), (b) (6)	27 Oct 2020 15:05:11

**US3632075**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 15:05:11

**US3632075**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 2013'	System	27 Oct 2020 15:05:11

**US3632075**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '2013'	System	27 Oct 2020 15:05:11

**US3632075**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 2013'	System	27 Oct 2020 15:05:11

**US3632075**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '2013'	System	27 Oct 2020 15:05:11

US3632075

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 09:15:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Non-site specific necrosis and vascular insufficiency NEC, PT: Peripheral venous disease, LLT: Venous peripheral insufficiency - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 08:24:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 08:24:02
Data point term sent to Coder	System	01 Dec 2020 18:28:53
User entered 'VENOUS INSUFFICIENCY IN RIGHT LEG'	(b) (4), (b) (6)	01 Dec 2020 18:28:43

**US3632075**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '01 UNK 2017'	(b) (4), (b) (6)	01 Dec 2020 18:28:43



**US3632075**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '0'	(b) (4), (b) (6)	01 Dec 2020 18:28:43

**US3632075**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 09:15:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Dec 2020 18:28:43

**US3632075**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered empty.	(b) (4), (b) (6)	01 Dec 2020 18:28:43

**US3632075**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:16:21
User entered '0'	(b) (4), (b) (6)	01 Dec 2020 18:28:43

**US3632075**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 2017'	System	01 Dec 2020 18:28:43

**US3632075**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '2017'	System	01 Dec 2020 18:28:43

**US3632075**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 09:15:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	01 Dec 2020 18:28:43

**US3632075**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	01 Dec 2020 18:28:43



US3632075

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 09:15:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:12:12
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure, LLT: Heart failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Mar 2021 16:37:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Mar 2021 16:37:13
Data point term sent to Coder	System	30 Mar 2021 16:36:15
User entered 'heart failure'	Christina Bacher (b) (4) (b) (4)	30 Mar 2021 16:36:02

US3632075

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 09:15:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:12:12
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '01 UNK 2005' reason for change:	System	30 Mar 2021 16:36:10
Data Entry Error	Christina Bacher (b) (4)	30 Mar 2021 16:36:10
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered ' 2005' (non-conformant).	System	30 Mar 2021 16:36:02
	Christina Bacher (b) (4)	30 Mar 2021 16:36:02
	(b) (4)	

US3632075

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 09:15:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:12:12
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
User entered '0'	(b) (4) Christina Bacher (b) (4) (b) (4)	30 Mar 2021 16:36:02

**US3632075**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 09:15:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:12:12
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
User entered 'Yes (Y)'	(b) (4) Christina Bacher (b) (4) (b) (4)	30 Mar 2021 16:36:02

US3632075

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 09:15:35

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:12:12
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
User entered empty.	(b) (4) Christina Bacher (b) (4) (b) (4)	30 Mar 2021 16:36:02

**US3632075**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:12:12
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
User entered '0'	(b) (4) Christina Bacher (b) (4) (b) (4)	30 Mar 2021 16:36:02

**US3632075**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 09:15:35**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 2005'	System	30 Mar 2021 16:36:10
User entered empty.	System	30 Mar 2021 16:36:02

**US3632075**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 09:15:35**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '2005'	System	30 Mar 2021 16:36:10
User entered empty.	System	30 Mar 2021 16:36:02



**US3632075**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	30 Mar 2021 16:36:02

**US3632075**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	30 Mar 2021 16:36:02

US3632075

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 09:15:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:12:17
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes zoster, LLT: Herpes zoster - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 17:20:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 17:20:37
Data point term sent to Coder	System	07 Apr 2021 17:20:03
User entered 'Herpes Zoster'	Isaac Perez (b) (4)	07 Apr 2021 17:19:27

**US3632075**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:12:17
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'UN Aug 2020'	(b) (4) Isaac Perez (b) (4) (b) (4)	07 Apr 2021 17:19:27

**US3632075**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:12:17
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '0'	(b) (4) Isaac Perez (b) (4) (b) (4)	07 Apr 2021 17:19:27

**US3632075**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 10 Jun 2021 09:15:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:12:17
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Yes (Y)'	(b) (4) Isaac Perez (b) (4) (b) (4)	07 Apr 2021 17:19:27

**US3632075**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 10 Jun 2021 09:15:35**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:12:17
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4) Isaac Perez (b) (4) (b) (4)	07 Apr 2021 17:19:27

**US3632075**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:12:17
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '0'	(b) (4) Isaac Perez (b) (4) (b) (4)	07 Apr 2021 17:19:27



**US3632075**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 10 Jun 2021 09:15:35**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Aug 2020'	System	07 Apr 2021 17:19:27

**US3632075**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 10 Jun 2021 09:15:35**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '2020'	System	07 Apr 2021 17:19:27

**US3632075**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	07 Apr 2021 17:19:27

**US3632075**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	07 Apr 2021 17:19:27

US3632075

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 09:15:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:41:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:37:22
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: General signs and symptoms NEC, PT: Peripheral swelling, LLT: Unilateral leg swelling - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 11:33:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 11:33:33
Data point term sent to Coder	System	16 Apr 2021 18:18:30
User entered 'chronic swelling of R leg'	Aastha KC (b) (4)	16 Apr 2021 18:18:06

**US3632075**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:41:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:37:22
User entered '01 Jan 2005'	Aastha KC (b) (4)	16 Apr 2021 18:18:06

**US3632075**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:41:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:37:22
User entered '0'	Aastha KC (b) (4)	16 Apr 2021 18:18:06

US3632075

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 09:15:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:41:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:37:22
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	16 Apr 2021 18:18:14
User entered 'Yes (Y)' reason for change: Data Entry Error	Aastha KC (b) (4) (b) (4)	16 Apr 2021 18:18:14
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	16 Apr 2021 18:18:06
User entered 'No (N)'	Aastha KC (b) (4) (b) (4)	16 Apr 2021 18:18:06



**US3632075**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 10 Jun 2021 09:15:35**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:41:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:37:22
User entered empty.	Aastha KC (b) (4)	16 Apr 2021 18:18:06

**US3632075**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:41:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:37:22
User entered '0'	Aastha KC (b) (4)	16 Apr 2021 18:18:06

**US3632075**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 10 Jun 2021 09:15:35**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'Jan 2005'	System	16 Apr 2021 18:18:06

**US3632075**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 10 Jun 2021 09:15:35**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '2005'	System	16 Apr 2021 18:18:06

**US3632075**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	16 Apr 2021 18:18:06

**US3632075**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 10 Jun 2021 09:15:35**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered empty.	System	16 Apr 2021 18:18:06

**US3632075**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:35**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 18:30:51

US3632075

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:17
User entered '11 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 18:30:51



**US3632075**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:35**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:17
User entered '13:43'	(b) (4), (b) (6)	14 Sep 2020 18:30:51

**US3632075**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:35**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '11 Sep 2020 13:43'	System	14 Sep 2020 18:30:51

US3632075

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:35

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:17
User entered '64.5' in	(b) (4), (b) (6)	14 Sep 2020 18:30:51
DataPoint set to visible.	System	11 Sep 2020 19:43:02

US3632075

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:35

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:17
User entered '186' lb	(b) (4), (b) (6)	14 Sep 2020 18:30:51
DataPoint set to visible.	System	11 Sep 2020 19:43:02

**US3632075**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:35**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered '31.49948'	System	14 Sep 2020 18:30:51
DataPoint set to visible.	System	11 Sep 2020 19:43:02

**US3632075**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:35**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'kg/m2'	System	14 Sep 2020 18:30:51
DataPoint set to visible.	System	11 Sep 2020 19:43:02

US3632075

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:17
User entered missing code ND - Not Done.	(b) (4), (b) (6)	14 Sep 2020 18:30:51

US3632075

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:17
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 18:30:51



**US3632075**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:35**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:17
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 18:30:51

**US3632075**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:35**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:17
User entered missing code ND - Not Done.	(b) (4), (b) (6)	14 Sep 2020 18:30:51

**US3632075**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:35**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'bpm'	System	14 Sep 2020 18:30:51

**US3632075**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:35**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:17
User entered missing code ND - Not Done.	(b) (4), (b) (6)	14 Sep 2020 18:30:51

US3632075

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'breaths/min'	System	14 Sep 2020 18:30:51

US3632075

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:17
User entered missing code ND - Not Done.	(b) (4), (b) (6)	14 Sep 2020 18:30:51

US3632075

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'mmHg'	System	14 Sep 2020 18:30:51

**US3632075**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:35**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:17
User entered missing code ND - Not Done.	(b) (4), (b) (6)	14 Sep 2020 18:30:51



**US3632075**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:35**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User entered 'mmHg'	System	14 Sep 2020 18:30:51

**US3632075**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:35**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14

**US3632075**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:35**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14

**US3632075**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:15:35**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:27:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 18:30:57

**US3632075**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:15:35**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:27:46
User entered '11 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 18:30:57

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[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:28:07
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 18:31:38

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Folder: Screening

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**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:28:07
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 18:31:38

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**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)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:28:07
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 18:31:38



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**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)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:28:07
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 18:31:38

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[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:28:07
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 18:31:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:35

[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)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:28:07
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 18:31:38

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Folder: Screening

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**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)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:28:07
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 18:31:38

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Folder: Screening

Form: Risk of Exposure

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[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)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:28:07
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 18:31:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:35

[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)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:28:07
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 18:31:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:35

**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)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:28:07
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 18:31:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:35

**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)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:28:07
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 18:31:38



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**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:15:35**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:28:07
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 18:31:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:35

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:28:07
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 18:31:38

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Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:31:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:35

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:28:07
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:31:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:35

**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)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:28:07
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:31:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:35

[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)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:28:07
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:31:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:35

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)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:28:07
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:31:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:35

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:28:07
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:31:38



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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:35

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
User entered 'I'	(b) (4), (b) (6)	14 Sep 2020 18:31:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:35

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:14
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:28:07
User entered 'grocery store, visit daughter, see friends'	(b) (4), (b) (6)	14 Sep 2020 18:31:38

**US3632075**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:35**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:28:24
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	11 Sep 2020 19:43:26

**US3632075**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:35**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:28:24
User entered '11 Sep 2020'	Sarah Wiatrek (b) (4)	11 Sep 2020 19:43:26

**US3632075**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:35**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:28:24
User entered 'Clinic (Clinic)'	Sarah Wiatrek (b) (4)	11 Sep 2020 19:43:26

**US3632075**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:35**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered 'VISIT1'	System	11 Sep 2020 19:43:26

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:15:35

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 17:29:10
User entered '11 SEP 2020'	RWS_ENDPOINT	11 Sep 2020 18:48:17
	ENDPOINT (b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:15:35

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 17:29:10
User entered '190645'	RWS_ENDPOINT	11 Sep 2020 18:48:17
	ENDPOINT (b) (4)	



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Folder: Visit 1 Day 1

Form: Randomization

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[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 17:29:10
User entered '>=65 years (3)'	RWS_ENDPOINT	11 Sep 2020 18:48:17
	ENDPOINT (b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

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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)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:29:10
User entered 'No (N)'	Sarah Wiatrek (b) (4)	11 Sep 2020 19:43:43

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:15:35

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)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:29:10
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	11 Sep 2020 19:43:43

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**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:15:35**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:29:10
User entered 'No (N)'	Sarah Wiatrek (b) (4)	11 Sep 2020 19:43:43

**US3632075**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:15:35**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:29:10
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	11 Sep 2020 19:43:43

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:15:35

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:29:10
User entered 'No (N)'	Sarah Wiatrek (b) (4)	11 Sep 2020 19:43:43

US3632075

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:15:35

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:29:10
User entered 'No (N)'	Isaac Perez (b) (4)	21 Sep 2020 16:55:15
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 06:12:47
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:12:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:15:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:30:27
User entered missing code ND - Not Done.	(b) (4), (b) (6)	14 Sep 2020 18:33:24



US3632075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:15:35

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:30:29
User entered missing code ND - Not Done.	(b) (4), (b) (6)	14 Sep 2020 18:33:24

US3632075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:15:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:30:27
User entered missing code ND - Not Done.	(b) (4), (b) (6)	14 Sep 2020 18:33:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:15:35

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:30:29
User entered missing code ND - Not Done.	(b) (4), (b) (6)	14 Sep 2020 18:33:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	14 Sep 2020 18:33:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:29:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 18:33:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:29:49
User entered '11 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 18:33:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:29:49
User entered '13:43'	(b) (4), (b) (6)	14 Sep 2020 18:33:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered '11 Sep 2020 13:43'	System	14 Sep 2020 18:33:24



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:29:49
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	22 Sep 2020 10:22:48
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Temperature was NCS' (Site from System).	Isaac Perez (b) (4)	21 Sep 2020 16:55:34
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:33:31
User entered '96.5' F	(b) (4), (b) (6)	14 Sep 2020 18:33:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:29:49
User entered 'Oral (Oral)'	(b) (4), (b) (6)	14 Sep 2020 18:33:24

**US3632075**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:35**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:29:49
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 18:33:24

US3632075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:29:49
User entered '63'	(b) (4), (b) (6)	14 Sep 2020 18:33:24

US3632075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered 'bpm'	System	14 Sep 2020 18:33:24

US3632075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:29:49
User entered '14'	(b) (4), (b) (6)	14 Sep 2020 18:33:24

US3632075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered 'breaths/min'	System	14 Sep 2020 18:33:24

US3632075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:29:49
User entered '131'	(b) (4), (b) (6)	14 Sep 2020 18:33:24



US3632075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered 'mmHg'	System	14 Sep 2020 18:33:24

US3632075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:29:49
User entered '79'	(b) (4), (b) (6)	14 Sep 2020 18:33:24

US3632075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered 'mmHg'	System	14 Sep 2020 18:33:24

US3632075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:15:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:30:27
User entered missing code ND - Not Done.	(b) (4), (b) (6)	14 Sep 2020 18:33:24

US3632075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:15:35

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:30:29
User entered missing code ND - Not Done.	(b) (4), (b) (6)	14 Sep 2020 18:33:24

US3632075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	14 Sep 2020 18:33:24

US3632075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:30:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 18:33:24

US3632075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:30:23
User entered '11 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 18:33:24



US3632075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:30:23
User entered '16:49'	(b) (4), (b) (6)	14 Sep 2020 18:33:24

US3632075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered '11 Sep 2020 16:49'	System	14 Sep 2020 18:33:24

US3632075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:30:23
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	22 Sep 2020 10:22:54
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Temperature was NCS' (Site from System).	Isaac Perez (b) (4)	21 Sep 2020 16:56:14
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:33:31
User entered '96.7' F	(b) (4), (b) (6)	14 Sep 2020 18:33:24

US3632075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:30:23
User entered 'Oral (Oral)'	(b) (4), (b) (6)	14 Sep 2020 18:33:24

**US3632075**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:35**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:30:23
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 18:33:24

US3632075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:30:23
User entered '71'	(b) (4), (b) (6)	14 Sep 2020 18:33:24

US3632075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered 'bpm'	System	14 Sep 2020 18:33:24

US3632075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:30:23
User entered '20'	(b) (4), (b) (6)	14 Sep 2020 18:33:24



US3632075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered 'breaths/min'	System	14 Sep 2020 18:33:24

US3632075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:30:23
User entered '151'	(b) (4), (b) (6)	14 Sep 2020 18:33:24

US3632075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered 'mmHg'	System	14 Sep 2020 18:33:24

US3632075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:30:23
User entered '74'	(b) (4), (b) (6)	14 Sep 2020 18:33:24

US3632075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered 'mmHg'	System	14 Sep 2020 18:33:24

US3632075

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:15:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:30:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 18:33:29

**US3632075**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:15:35**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:30:34
User entered '11 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 18:33:29

US3632075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:15:35

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:31:13
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	11 Sep 2020 20:25:16



US3632075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:15:35

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:31:13
User entered empty.	Sarah Wiatrek (b) (4)	11 Sep 2020 20:25:16

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:15:35

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)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:31:13
User entered empty.	Sarah Wiatrek (b) (4)	11 Sep 2020 20:25:16

**US3632075**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:15:35**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 20:25:16

US3632075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:15:35

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:31:13
User entered '11 Sep 2020'	Sarah Wiatrek (b) (4)	11 Sep 2020 20:25:16

US3632075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:15:35

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:31:13
User entered '16:18'	Sarah Wiatrek (b) (4)	11 Sep 2020 20:25:16

US3632075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:15:35

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered '11 Sep 2020 16:18'	System	11 Sep 2020 20:25:16

US3632075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:15:35

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:31:13
User entered 'Right Arm (RIGHT ARM)'	Sarah Wiatrek (b) (4)	11 Sep 2020 20:25:16

US3632075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:15:35

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:31:13
User entered 'ONCE'	System	11 Sep 2020 20:25:16



US3632075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:15:35

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 20:25:16

US3632075

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:15:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:31:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 18:33:46

US3632075

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:15:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:31:50
User entered '11 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 18:33:46

US3632075

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:15:35

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:31:50
User entered '15:15'	(b) (4), (b) (6)	14 Sep 2020 18:33:46

US3632075

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:15:35

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered '11 Sep 2020 15:15'	System	14 Sep 2020 18:33:46

US3632075

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:15:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:32:02
User entered '11 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 18:33:53

**US3632075**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	14 Sep 2020 18:33:53

US3632075

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:15:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:32:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 18:33:53



US3632075

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:15:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:32:02
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	14 Sep 2020 18:34:02
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	14 Sep 2020 18:34:02
User entered '15:20' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 18:34:02
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	14 Sep 2020 18:33:53
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 18:33:53

**US3632075**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered '11 Sep 2020 15:20'	System	14 Sep 2020 18:34:02
User entered empty.	System	14 Sep 2020 18:33:53

**US3632075**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	14 Sep 2020 18:33:53

**US3632075**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:32:02
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 18:33:53

**US3632075**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:15:35**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:32:02
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 18:33:53

**US3632075**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered empty.	System	14 Sep 2020 18:33:53

US3632075

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:15:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:32:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 18:34:07

**US3632075**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered 'I'	System	14 Sep 2020 18:34:07



US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	11 Sep 2020 20:25:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-11T16:54:59', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '0c57b504-81e0-4ec2-b349-cbf788c223ca'	System	11 Sep 2020 20:56:19
User entered 'Yes (Y)'	System	11 Sep 2020 20:56:19

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-11T16:55:39', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '0c57b504-81e0-4ec2-b349-cbf788c223ca'	System	11 Sep 2020 20:56:19
User entered '96.7'	System	11 Sep 2020 20:56:19

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabb9e8d62)', Time: '2020-09-11T16:55:51', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '0c57b504-81e0-4ec2-b349-cbf788c223ca'	System	11 Sep 2020 20:56:19
User entered 'No (N)'	System	11 Sep 2020 20:56:19

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabb9e8d62)', Time: '2020-09-11T16:56:16', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '0c57b504-81e0-4ec2-b349-cbf788c223ca'	System	11 Sep 2020 20:56:19
User entered '11 Sep 2020 16:56'	System	11 Sep 2020 20:56:19

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '11 Sep 2020 16:38'	System	11 Sep 2020 20:25:16

**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '11 Sep 2020 19:08'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	11 Sep 2020 20:25:16
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 20:25:16



US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-11T21:31:28', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'ad38b309-b5c8-4d2e-9d2b-524435510c78'	System	12 Sep 2020 01:32:30
User entered 'Yes (Y)'	System	12 Sep 2020 01:32:30

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-11T21:32:01', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'ad38b309-b5c8-4d2e-9d2b-524435510c78'	System	12 Sep 2020 01:32:30
User entered '96.4'	System	12 Sep 2020 01:32:30

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-11T21:32:07', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'ad38b309-b5c8-4d2e-9d2b-524435510c78'	System	12 Sep 2020 01:32:30
User entered 'No (N)'	System	12 Sep 2020 01:32:30

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-11T21:32:27', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'ad38b309-b5c8-4d2e-9d2b-524435510c78'	System	12 Sep 2020 01:32:30
User entered '11 Sep 2020 21:32'	System	12 Sep 2020 01:32:30

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '11 Sep 2020 20:03'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	11 Sep 2020 20:25:16
User entered 'Day 2'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:15:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-12T20:06:12', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '5dd07456-0c5c-46ee-afd4-e8685e60c307'	System	13 Sep 2020 00:08:12
User entered 'Yes (Y)'	System	13 Sep 2020 00:08:12



US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:15:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-12T20:06:24', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '5dd07456-0c5c-46ee-afd4-e8685e60c307'	System	13 Sep 2020 00:08:12
User entered '97.9'	System	13 Sep 2020 00:08:12

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:15:35

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-12T20:06:30', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '5dd07456-0c5c-46ee-afd4-e8685e60c307'	System	13 Sep 2020 00:08:12
User entered 'No (N)'	System	13 Sep 2020 00:08:12

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:15:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-12T20:06:43', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '5dd07456-0c5c-46ee-afd4-e8685e60c307'	System	13 Sep 2020 00:08:12
User entered '12 Sep 2020 20:06'	System	13 Sep 2020 00:08:12

**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:15:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	11 Sep 2020 20:25:16
User entered 'Day 3'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:15:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-13T18:46:53', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '10f48a33-079b-4348-84d9-8811d0a590bc'	System	13 Sep 2020 22:47:07
User entered 'Yes (Y)'	System	13 Sep 2020 22:47:07

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:15:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-13T18:46:39', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '10f48a33-079b-4348-84d9-8811d0a590bc'	System	13 Sep 2020 22:47:07
User entered '97.6'	System	13 Sep 2020 22:47:07



US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:15:35

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-13T18:46:47', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '10f48a33-079b-4348-84d9-8811d0a590bc'	System	13 Sep 2020 22:47:07
User entered 'No (N)'	System	13 Sep 2020 22:47:07

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:15:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-13T18:47:02', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '10f48a33-079b-4348-84d9-8811d0a590bc'	System	13 Sep 2020 22:47:07
User entered '13 Sep 2020 18:47'	System	13 Sep 2020 22:47:07

**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:15:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	11 Sep 2020 20:25:16
User entered 'Day 4'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:15:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-14T20:16:31', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '39d1683f-6287-439c-9d06-08193577f653'	System	15 Sep 2020 00:17:13
User entered 'Yes (Y)'	System	15 Sep 2020 00:17:13

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:15:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-14T20:16:54', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '39d1683f-6287-439c-9d06-08193577f653'	System	15 Sep 2020 00:17:13
User entered '96.7'	System	15 Sep 2020 00:17:13

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:15:35

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-14T20:17:01', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '39d1683f-6287-439c-9d06-08193577f653'	System	15 Sep 2020 00:17:13
User entered 'No (N)'	System	15 Sep 2020 00:17:13



US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:15:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-14T20:17:10', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '39d1683f-6287-439c-9d06-08193577f653'	System	15 Sep 2020 00:17:13
User entered '14 Sep 2020 20:17'	System	15 Sep 2020 00:17:13

**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:15:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	11 Sep 2020 20:25:16
User entered 'Day 5'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:15:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-15T20:22:49', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '5bfac24a-5a9e-4831-badb-92ea9f53e2f5'	System	16 Sep 2020 00:23:04
User entered 'Yes (Y)'	System	16 Sep 2020 00:23:04

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:15:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-15T20:22:38', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '5bfac24a-5a9e-4831-badb-92ea9f53e2f5'	System	16 Sep 2020 00:23:04
User entered '97.7'	System	16 Sep 2020 00:23:04

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:15:35

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-15T20:22:43', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '5bfac24a-5a9e-4831-badb-92ea9f53e2f5'	System	16 Sep 2020 00:23:04
User entered 'No (N)'	System	16 Sep 2020 00:23:04

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:15:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-15T20:22:58', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '5bfac24a-5a9e-4831-badb-92ea9f53e2f5'	System	16 Sep 2020 00:23:04
User entered '15 Sep 2020 20:22'	System	16 Sep 2020 00:23:04



**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 20:25:16

**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	11 Sep 2020 20:25:16
User entered 'Day 6'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:15:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-16T18:42:38', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'bb264154-c771-40e0-aef8-f79910cc9445'	System	16 Sep 2020 22:43:09
User entered 'Yes (Y)'	System	16 Sep 2020 22:43:09

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:15:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-16T18:42:50', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'bb264154-c771-40e0-aef8-f79910cc9445'	System	16 Sep 2020 22:43:09
User entered '96.4'	System	16 Sep 2020 22:43:09

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:15:35

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabb9e8d62)', Time: '2020-09-16T18:42:55', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'bb264154-c771-40e0-aef8-f79910cc9445'	System	16 Sep 2020 22:43:09
User entered 'No (N)'	System	16 Sep 2020 22:43:09

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:15:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-16T18:43:03', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'bb264154-c771-40e0-aef8-f79910cc9445'	System	16 Sep 2020 22:43:09
User entered '16 Sep 2020 18:43'	System	16 Sep 2020 22:43:09

**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 20:25:16



**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	11 Sep 2020 20:25:16
User entered 'Day 7'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:15:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-17T19:43:16', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '919d3810-af28-4aff-b0d3-1d3766b8ef5b'	System	17 Sep 2020 23:43:40
User entered 'Yes (Y)'	System	17 Sep 2020 23:43:40

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:15:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabb9e8d62)', Time: '2020-09-17T19:43:25', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '919d3810-af28-4aff-b0d3-1d3766b8ef5b'	System	17 Sep 2020 23:43:40
User entered '97.1'	System	17 Sep 2020 23:43:40

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:15:35

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-17T19:43:30', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '919d3810-af28-4aff-b0d3-1d3766b8ef5b'	System	17 Sep 2020 23:43:40
User entered 'No (N)'	System	17 Sep 2020 23:43:40

US3632075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:15:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-17T19:43:37', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '919d3810-af28-4aff-b0d3-1d3766b8ef5b'	System	17 Sep 2020 23:43:40
User entered '17 Sep 2020 19:43'	System	17 Sep 2020 23:43:40

**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 20:25:16

**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 20:25:16



US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
Data entry locked.	System	11 Sep 2020 20:25:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-11T16:56:41', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '3ae4549b-4c5e-4c17-a0e7-d91a5bb04dae'	System	11 Sep 2020 20:58:04
User entered 'None (1)'	System	11 Sep 2020 20:58:04

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-11T16:56:57', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '3ae4549b-4c5e-4c17-a0e7-d91a5bb04dae'	System	11 Sep 2020 20:58:04
User entered 'No (N)'	System	11 Sep 2020 20:58:04

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-11T16:57:08', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '3ae4549b-4c5e-4c17-a0e7-d91a5bb04dae'	System	11 Sep 2020 20:58:04
User entered 'No (N)'	System	11 Sep 2020 20:58:04

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-11T16:57:43', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '3ae4549b-4c5e-4c17-a0e7-d91a5bb04dae'	System	11 Sep 2020 20:58:04
User entered 'None (1)'	System	11 Sep 2020 20:58:04

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-11T16:58:01', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '3ae4549b-4c5e-4c17-a0e7-d91a5bb04dae'	System	11 Sep 2020 20:58:04
User entered '11 Sep 2020 16:58'	System	11 Sep 2020 20:58:04

**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
User entered '11 Sep 2020 16:38'	System	11 Sep 2020 20:25:16

**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
User entered '11 Sep 2020 19:08'	System	11 Sep 2020 20:25:16



US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
Data entry locked.	System	11 Sep 2020 20:25:16
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-11T21:32:41', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'c0164e21-50a2-4f85-935b-18065d58a086'	System	12 Sep 2020 01:33:28
User entered 'None (1)'	System	12 Sep 2020 01:33:28

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-11T21:32:46', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'c0164e21-50a2-4f85-935b-18065d58a086'	System	12 Sep 2020 01:33:28
User entered 'No (N)'	System	12 Sep 2020 01:33:28

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-11T21:32:51', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'c0164e21-50a2-4f85-935b-18065d58a086'	System	12 Sep 2020 01:33:28
User entered 'No (N)'	System	12 Sep 2020 01:33:28

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-11T21:33:16', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'c0164e21-50a2-4f85-935b-18065d58a086'	System	12 Sep 2020 01:33:28
User entered 'None (1)'	System	12 Sep 2020 01:33:28

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-11T21:33:25', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'c0164e21-50a2-4f85-935b-18065d58a086'	System	12 Sep 2020 01:33:28
User entered '11 Sep 2020 21:33'	System	12 Sep 2020 01:33:28

**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
User entered '11 Sep 2020 20:03'	System	11 Sep 2020 20:25:16

**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 20:25:16



US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
Data entry locked.	System	11 Sep 2020 20:25:16
User entered 'Day 2'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:15:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-12T20:07:01', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'bd37eb3f-12a1-4faa-b62f-7a3170bcc168'	System	13 Sep 2020 00:09:19
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 00:09:19

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:15:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-12T20:07:09', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'bd37eb3f-12a1-4faa-b62f-7a3170bcc168'	System	13 Sep 2020 00:09:19
User entered 'No (N)'	System	13 Sep 2020 00:09:19

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:15:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-12T20:07:38', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'bd37eb3f-12a1-4faa-b62f-7a3170bcc168'	System	13 Sep 2020 00:09:19
User entered 'No (N)'	System	13 Sep 2020 00:09:19

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:15:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-12T20:07:47', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'bd37eb3f-12a1-4faa-b62f-7a3170bcc168'	System	13 Sep 2020 00:09:19
User entered 'None (1)'	System	13 Sep 2020 00:09:19

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:15:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-12T20:08:08', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'bd37eb3f-12a1-4faa-b62f-7a3170bcc168'	System	13 Sep 2020 00:09:19
User entered '12 Sep 2020 20:08'	System	13 Sep 2020 00:09:19

**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 20:25:16

**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 20:25:16



US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
Data entry locked.	System	11 Sep 2020 20:25:16
User entered 'Day 3'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:15:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-13T18:47:13', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '72b23ecc-a70e-43a4-9bd9-44a7cf21f64e'	System	13 Sep 2020 22:48:00
User entered 'None (1)'	System	13 Sep 2020 22:48:00

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:15:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-13T18:47:17', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '72b23ecc-a70e-43a4-9bd9-44a7cf21f64e'	System	13 Sep 2020 22:48:00
User entered 'No (N)'	System	13 Sep 2020 22:48:00

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:15:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-13T18:47:22', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '72b23ecc-a70e-43a4-9bd9-44a7cf21f64e'	System	13 Sep 2020 22:48:00
User entered 'No (N)'	System	13 Sep 2020 22:48:00

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:15:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-13T18:47:44', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '72b23ecc-a70e-43a4-9bd9-44a7cf21f64e'	System	13 Sep 2020 22:48:00
User entered 'None (1)'	System	13 Sep 2020 22:48:00

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:15:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-13T18:47:56', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '72b23ecc-a70e-43a4-9bd9-44a7cf21f64e'	System	13 Sep 2020 22:48:00
User entered '13 Sep 2020 18:47'	System	13 Sep 2020 22:48:00

**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:15:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 20:25:16



US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
Data entry locked.	System	11 Sep 2020 20:25:16
User entered 'Day 4'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:15:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-14T20:17:30', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '4df8505d-37ca-4588-b125-033e63899b6d'	System	15 Sep 2020 00:17:58
User entered 'None (1)'	System	15 Sep 2020 00:17:58

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:15:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-14T20:17:35', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '4df8505d-37ca-4588-b125-033e63899b6d'	System	15 Sep 2020 00:17:58
User entered 'No (N)'	System	15 Sep 2020 00:17:58

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:15:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-14T20:17:40', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '4df8505d-37ca-4588-b125-033e63899b6d'	System	15 Sep 2020 00:17:58
User entered 'No (N)'	System	15 Sep 2020 00:17:58

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:15:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-14T20:17:45', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '4df8505d-37ca-4588-b125-033e63899b6d'	System	15 Sep 2020 00:17:58
User entered 'None (1)'	System	15 Sep 2020 00:17:58

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:15:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-14T20:17:55', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '4df8505d-37ca-4588-b125-033e63899b6d'	System	15 Sep 2020 00:17:58
User entered '14 Sep 2020 20:17'	System	15 Sep 2020 00:17:58

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:15:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:15:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 20:25:16



US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
Data entry locked.	System	11 Sep 2020 20:25:16
User entered 'Day 5'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:15:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-15T20:23:37', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'df44f1ec-116b-4596-b46e-d57739b79aa8'	System	16 Sep 2020 00:31:52
User entered 'None (1)'	System	16 Sep 2020 00:31:52

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:15:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-15T20:31:13', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'df44f1ec-116b-4596-b46e-d57739b79aa8'	System	16 Sep 2020 00:31:52
User entered 'No (N)'	System	16 Sep 2020 00:31:52

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:15:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-15T20:31:17', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'df44f1ec-116b-4596-b46e-d57739b79aa8'	System	16 Sep 2020 00:31:52
User entered 'No (N)'	System	16 Sep 2020 00:31:52

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:15:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-15T20:31:31', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'df44f1ec-116b-4596-b46e-d57739b79aa8'	System	16 Sep 2020 00:31:52
User entered 'None (1)'	System	16 Sep 2020 00:31:52

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:15:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-15T20:31:49', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'df44f1ec-116b-4596-b46e-d57739b79aa8'	System	16 Sep 2020 00:31:52
User entered '15 Sep 2020 20:31'	System	16 Sep 2020 00:31:52

**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 20:25:16

**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 20:25:16



US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
Data entry locked.	System	11 Sep 2020 20:25:16
User entered 'Day 6'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:15:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-16T18:43:12', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '0d31f62f-693e-4781-92da-219bd4980806'	System	16 Sep 2020 22:43:36
User entered 'None (1)'	System	16 Sep 2020 22:43:36

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:15:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-16T18:43:17', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '0d31f62f-693e-4781-92da-219bd4980806'	System	16 Sep 2020 22:43:36
User entered 'No (N)'	System	16 Sep 2020 22:43:36

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:15:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-16T18:43:22', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '0d31f62f-693e-4781-92da-219bd4980806'	System	16 Sep 2020 22:43:36
User entered 'No (N)'	System	16 Sep 2020 22:43:36

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:15:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-16T18:43:26', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '0d31f62f-693e-4781-92da-219bd4980806'	System	16 Sep 2020 22:43:36
User entered 'None (1)'	System	16 Sep 2020 22:43:36

**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-16T18:43:32', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '0d31f62f-693e-4781-92da-219bd4980806'	System	16 Sep 2020 22:43:36
User entered '16 Sep 2020 18:43'	System	16 Sep 2020 22:43:36

**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 20:25:16

**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 20:25:16



US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
Data entry locked.	System	11 Sep 2020 20:25:16
User entered 'Day 7'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:15:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-17T19:43:45', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '7eceeac4-7be7-4727-a486-1e06f9b64085'	System	17 Sep 2020 23:44:09
User entered 'None (1)'	System	17 Sep 2020 23:44:09

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:15:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabb9e8d62)', Time: '2020-09-17T19:43:49', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '7eceeac4-7be7-4727-a486-1e06f9b64085'	System	17 Sep 2020 23:44:09
User entered 'No (N)'	System	17 Sep 2020 23:44:09

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:15:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-17T19:43:53', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '7eceeac4-7be7-4727-a486-1e06f9b64085'	System	17 Sep 2020 23:44:09
User entered 'No (N)'	System	17 Sep 2020 23:44:09

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:15:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-17T19:43:57', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '7eceeac4-7be7-4727-a486-1e06f9b64085'	System	17 Sep 2020 23:44:09
User entered 'None (1)'	System	17 Sep 2020 23:44:09

US3632075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:15:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-17T19:44:06', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '7eceeac4-7be7-4727-a486-1e06f9b64085'	System	17 Sep 2020 23:44:09
User entered '17 Sep 2020 19:44'	System	17 Sep 2020 23:44:09

**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 20:25:16

**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 20:25:16



US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
Data entry locked.	System	11 Sep 2020 20:25:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-11T16:58:15', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '4a63386b-8fe9-4451-81a4-51b9750b5332'	System	11 Sep 2020 21:00:06
User entered 'None (0)'	System	11 Sep 2020 21:00:06

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-11T16:58:50', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '4a63386b-8fe9-4451-81a4-51b9750b5332'	System	11 Sep 2020 21:00:06
User entered 'None (0)'	System	11 Sep 2020 21:00:06

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-11T16:59:00', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '4a63386b-8fe9-4451-81a4-51b9750b5332'	System	11 Sep 2020 21:00:06
User entered 'None (0)'	System	11 Sep 2020 21:00:06

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-11T16:59:09', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '4a63386b-8fe9-4451-81a4-51b9750b5332'	System	11 Sep 2020 21:00:06
User entered 'None (0)'	System	11 Sep 2020 21:00:06

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-11T16:59:18', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '4a63386b-8fe9-4451-81a4-51b9750b5332'	System	11 Sep 2020 21:00:06
User entered 'None (0)'	System	11 Sep 2020 21:00:06

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-11T16:59:22', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '4a63386b-8fe9-4451-81a4-51b9750b5332'	System	11 Sep 2020 21:00:06
User entered 'None (0)'	System	11 Sep 2020 21:00:06

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-11T16:59:46', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '4a63386b-8fe9-4451-81a4-51b9750b5332'	System	11 Sep 2020 21:00:06
User entered 'No (N)'	System	11 Sep 2020 21:00:06



US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-11T17:00:01', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '4a63386b-8fe9-4451-81a4-51b9750b5332'	System	11 Sep 2020 21:00:06
User entered '11 Sep 2020 17:00'	System	11 Sep 2020 21:00:06

**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
User entered '11 Sep 2020 16:38'	System	11 Sep 2020 20:25:16

**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
User entered '11 Sep 2020 19:08'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
Data entry locked.	System	11 Sep 2020 20:25:16
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-11T21:33:34', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '8f45778a-0fe4-4dd1-9339-e7a21131ea01'	System	12 Sep 2020 01:34:22
User entered 'None (0)'	System	12 Sep 2020 01:34:22

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-11T21:33:41', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '8f45778a-0fe4-4dd1-9339-e7a21131ea01'	System	12 Sep 2020 01:34:22
User entered 'None (0)'	System	12 Sep 2020 01:34:22

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-11T21:33:46', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '8f45778a-0fe4-4dd1-9339-e7a21131ea01'	System	12 Sep 2020 01:34:22
User entered 'None (0)'	System	12 Sep 2020 01:34:22

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-11T21:33:50', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '8f45778a-0fe4-4dd1-9339-e7a21131ea01'	System	12 Sep 2020 01:34:22
User entered 'None (0)'	System	12 Sep 2020 01:34:22



US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-11T21:33:54', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '8f45778a-0fe4-4dd1-9339-e7a21131ea01'	System	12 Sep 2020 01:34:22
User entered 'None (0)'	System	12 Sep 2020 01:34:22

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-11T21:33:57', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '8f45778a-0fe4-4dd1-9339-e7a21131ea01'	System	12 Sep 2020 01:34:22
User entered 'None (0)'	System	12 Sep 2020 01:34:22

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-11T21:34:03', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '8f45778a-0fe4-4dd1-9339-e7a21131ea01'	System	12 Sep 2020 01:34:22
User entered 'No (N)'	System	12 Sep 2020 01:34:22

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-11T21:34:18', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '8f45778a-0fe4-4dd1-9339-e7a21131ea01'	System	12 Sep 2020 01:34:22
User entered '11 Sep 2020 21:34'	System	12 Sep 2020 01:34:22

**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
User entered '11 Sep 2020 20:03'	System	11 Sep 2020 20:25:16

**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
Data entry locked.	System	11 Sep 2020 20:25:16
User entered 'Day 2'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:15:35

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-12T20:08:19', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'a966236e-432f-49ea-8fd5-f649853ec6aa'	System	13 Sep 2020 00:09:45
User entered 'None (0)'	System	13 Sep 2020 00:09:45



US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:15:35

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-12T20:08:24', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'a966236e-432f-49ea-8fd5-f649853ec6aa'	System	13 Sep 2020 00:09:45
User entered 'None (0)'	System	13 Sep 2020 00:09:45

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:15:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-12T20:08:29', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'a966236e-432f-49ea-8fd5-f649853ec6aa'	System	13 Sep 2020 00:09:45
User entered 'None (0)'	System	13 Sep 2020 00:09:45

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:15:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-12T20:08:33', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'a966236e-432f-49ea-8fd5-f649853ec6aa'	System	13 Sep 2020 00:09:45
User entered 'None (0)'	System	13 Sep 2020 00:09:45

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:15:35

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-12T20:08:36', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'a966236e-432f-49ea-8fd5-f649853ec6aa'	System	13 Sep 2020 00:09:45
User entered 'None (0)'	System	13 Sep 2020 00:09:45

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:15:35

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-12T20:08:41', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'a966236e-432f-49ea-8fd5-f649853ec6aa'	System	13 Sep 2020 00:09:45
User entered 'None (0)'	System	13 Sep 2020 00:09:45

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:15:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-12T20:08:46', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'a966236e-432f-49ea-8fd5-f649853ec6aa'	System	13 Sep 2020 00:09:45
User entered 'No (N)'	System	13 Sep 2020 00:09:45

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:15:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-12T20:09:01', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'a966236e-432f-49ea-8fd5-f649853ec6aa'	System	13 Sep 2020 00:09:45
User entered '12 Sep 2020 20:09'	System	13 Sep 2020 00:09:45

**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 20:25:16



**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
Data entry locked.	System	11 Sep 2020 20:25:16
User entered 'Day 3'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:15:35

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-13T18:48:12', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '0d7bf351-342e-4890-b58a-4771fd40a23c'	System	13 Sep 2020 22:49:08
User entered 'None (0)'	System	13 Sep 2020 22:49:08

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:15:35

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-13T18:48:23', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '0d7bf351-342e-4890-b58a-4771fd40a23c'	System	13 Sep 2020 22:49:08
User entered 'None (0)'	System	13 Sep 2020 22:49:08

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:15:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-13T18:48:28', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '0d7bf351-342e-4890-b58a-4771fd40a23c'	System	13 Sep 2020 22:49:08
User entered 'None (0)'	System	13 Sep 2020 22:49:08

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:15:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-13T18:48:31', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '0d7bf351-342e-4890-b58a-4771fd40a23c'	System	13 Sep 2020 22:49:08
User entered 'None (0)'	System	13 Sep 2020 22:49:08

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:15:35

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-13T18:48:37', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '0d7bf351-342e-4890-b58a-4771fd40a23c'	System	13 Sep 2020 22:49:08
User entered 'None (0)'	System	13 Sep 2020 22:49:08

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:15:35

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabb9e8d62)', Time: '2020-09-13T18:48:42', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '0d7bf351-342e-4890-b58a-4771fd40a23c'	System	13 Sep 2020 22:49:08
User entered 'None (0)'	System	13 Sep 2020 22:49:08



US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:15:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-13T18:48:49', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '0d7bf351-342e-4890-b58a-4771fd40a23c'	System	13 Sep 2020 22:49:08
User entered 'No (N)'	System	13 Sep 2020 22:49:08

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:15:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-13T18:49:02', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '0d7bf351-342e-4890-b58a-4771fd40a23c'	System	13 Sep 2020 22:49:08
User entered '13 Sep 2020 18:49'	System	13 Sep 2020 22:49:08

**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 20:25:16

**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
Data entry locked.	System	11 Sep 2020 20:25:16
User entered 'Day 4'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:15:35

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-14T20:18:02', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '8045edf6-79ca-4128-af45-abb69a26e52a'	System	15 Sep 2020 00:19:05
User entered 'None (0)'	System	15 Sep 2020 00:19:05

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:15:35

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-14T20:18:06', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '8045edf6-79ca-4128-af45-abb69a26e52a'	System	15 Sep 2020 00:19:05
User entered 'None (0)'	System	15 Sep 2020 00:19:05

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:15:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-14T20:18:10', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '8045edf6-79ca-4128-af45-abb69a26e52a'	System	15 Sep 2020 00:19:05
User entered 'None (0)'	System	15 Sep 2020 00:19:05



US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:15:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-14T20:18:21', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '8045edf6-79ca-4128-af45-abb69a26e52a'	System	15 Sep 2020 00:19:05
User entered 'None (0)'	System	15 Sep 2020 00:19:05

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:15:35

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-14T20:18:27', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '8045edf6-79ca-4128-af45-abb69a26e52a'	System	15 Sep 2020 00:19:05
User entered 'None (0)'	System	15 Sep 2020 00:19:05

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:15:35

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-14T20:18:30', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '8045edf6-79ca-4128-af45-abb69a26e52a'	System	15 Sep 2020 00:19:05
User entered 'None (0)'	System	15 Sep 2020 00:19:05

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:15:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-14T20:18:40', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '8045edf6-79ca-4128-af45-abb69a26e52a'	System	15 Sep 2020 00:19:05
User entered 'No (N)'	System	15 Sep 2020 00:19:05

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:15:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-14T20:18:59', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '8045edf6-79ca-4128-af45-abb69a26e52a'	System	15 Sep 2020 00:19:05
User entered '14 Sep 2020 20:18'	System	15 Sep 2020 00:19:05

**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 20:25:16

**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
Data entry locked.	System	11 Sep 2020 20:25:16
User entered 'Day 5'	System	11 Sep 2020 20:25:16



US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:15:35

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-15T20:31:58', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '1ee81953-ece5-422f-9772-480b66fa0c16'	System	16 Sep 2020 00:32:44
User entered 'None (0)'	System	16 Sep 2020 00:32:44

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:15:35

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-15T20:32:03', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '1ee81953-ece5-422f-9772-480b66fa0c16'	System	16 Sep 2020 00:32:44
User entered 'None (0)'	System	16 Sep 2020 00:32:44

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:15:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-15T20:32:10', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '1ee81953-ece5-422f-9772-480b66fa0c16'	System	16 Sep 2020 00:32:44
User entered 'None (0)'	System	16 Sep 2020 00:32:44

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:15:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-15T20:32:14', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '1ee81953-ece5-422f-9772-480b66fa0c16'	System	16 Sep 2020 00:32:44
User entered 'None (0)'	System	16 Sep 2020 00:32:44

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:15:35

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-15T20:32:18', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '1ee81953-ece5-422f-9772-480b66fa0c16'	System	16 Sep 2020 00:32:44
User entered 'None (0)'	System	16 Sep 2020 00:32:44

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:15:35

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-15T20:32:21', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '1ee81953-ece5-422f-9772-480b66fa0c16'	System	16 Sep 2020 00:32:44
User entered 'None (0)'	System	16 Sep 2020 00:32:44

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:15:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-15T20:32:27', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '1ee81953-ece5-422f-9772-480b66fa0c16'	System	16 Sep 2020 00:32:44
User entered 'No (N)'	System	16 Sep 2020 00:32:44

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:15:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-15T20:32:40', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '1ee81953-ece5-422f-9772-480b66fa0c16'	System	16 Sep 2020 00:32:44
User entered '15 Sep 2020 20:32'	System	16 Sep 2020 00:32:44



US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:15:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 20:25:16

**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
Data entry locked.	System	11 Sep 2020 20:25:16
User entered 'Day 6'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:15:35

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-16T18:43:39', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'e20ace6f-bc47-43a8-a8a9-a546f44cb6fe'	System	16 Sep 2020 22:44:27
User entered 'None (0)'	System	16 Sep 2020 22:44:27

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:15:35

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-16T18:43:49', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'e20ace6f-bc47-43a8-a8a9-a546f44cb6fe'	System	16 Sep 2020 22:44:27
User entered 'Some interference with activity (2)'	System	16 Sep 2020 22:44:27

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:15:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-16T18:43:53', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'e20ace6f-bc47-43a8-a8a9-a546f44cb6fe'	System	16 Sep 2020 22:44:27
User entered 'None (0)'	System	16 Sep 2020 22:44:27

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:15:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-16T18:43:57', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'e20ace6f-bc47-43a8-a8a9-a546f44cb6fe'	System	16 Sep 2020 22:44:27
User entered 'None (0)'	System	16 Sep 2020 22:44:27

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:15:35

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-16T18:44:01', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'e20ace6f-bc47-43a8-a8a9-a546f44cb6fe'	System	16 Sep 2020 22:44:27
User entered 'None (0)'	System	16 Sep 2020 22:44:27



US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:15:35

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-16T18:44:05', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'e20ace6f-bc47-43a8-a8a9-a546f44cb6fe'	System	16 Sep 2020 22:44:27
User entered 'None (0)'	System	16 Sep 2020 22:44:27

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:15:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-16T18:44:08', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'e20ace6f-bc47-43a8-a8a9-a546f44cb6fe'	System	16 Sep 2020 22:44:27
User entered 'No (N)'	System	16 Sep 2020 22:44:27

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:15:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-16T18:44:21', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'e20ace6f-bc47-43a8-a8a9-a546f44cb6fe'	System	16 Sep 2020 22:44:27
User entered '16 Sep 2020 18:44'	System	16 Sep 2020 22:44:27

**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 20:25:16

**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
Data entry locked.	System	11 Sep 2020 20:25:16
User entered 'Day 7'	System	11 Sep 2020 20:25:16

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:15:35

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-17T19:44:12', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '8e1e35da-c002-4116-919c-bcacc14daef4'	System	17 Sep 2020 23:44:58
User entered 'None (0)'	System	17 Sep 2020 23:44:58

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:15:35

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-17T19:44:19', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '8e1e35da-c002-4116-919c-bcacc14daef4'	System	17 Sep 2020 23:44:58
User entered 'None (0)'	System	17 Sep 2020 23:44:58



US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:15:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-17T19:44:22', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '8e1e35da-c002-4116-919c-bcacc14daef4'	System	17 Sep 2020 23:44:58
User entered 'None (0)'	System	17 Sep 2020 23:44:58

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:15:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-17T19:44:26', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '8e1e35da-c002-4116-919c-bcacc14daef4'	System	17 Sep 2020 23:44:58
User entered 'None (0)'	System	17 Sep 2020 23:44:58

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:15:35

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-17T19:44:33', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '8e1e35da-c002-4116-919c-bcacc14daef4'	System	17 Sep 2020 23:44:58
User entered 'None (0)'	System	17 Sep 2020 23:44:58

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:15:35

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-17T19:44:36', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '8e1e35da-c002-4116-919c-bcacc14daef4'	System	17 Sep 2020 23:44:58
User entered 'None (0)'	System	17 Sep 2020 23:44:58

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:15:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-17T19:44:43', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '8e1e35da-c002-4116-919c-bcacc14daef4'	System	17 Sep 2020 23:44:58
User entered 'No (N)'	System	17 Sep 2020 23:44:58

US3632075

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:15:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-09-17T19:44:56', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '8e1e35da-c002-4116-919c-bcacc14daef4'	System	17 Sep 2020 23:44:58
User entered '17 Sep 2020 19:44'	System	17 Sep 2020 23:44:58

**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 20:25:16

**US3632075**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:48
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 20:25:16



**US3632075**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:35**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:32:58
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	18 Sep 2020 16:59:33

**US3632075**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:35**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:32:58
User entered '18 Sep 2020'	Sarah Wiatrek (b) (4)	18 Sep 2020 16:59:33

US3632075

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:32:58
User entered 'Contact Made (CONTACT MADE)'	Sarah Wiatrek (b) (4)	18 Sep 2020 16:59:33

US3632075

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:35

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:32:58
User entered empty.	Sarah Wiatrek (b) (4)	18 Sep 2020 16:59:33

**US3632075**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:35**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:33:37
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	18 Sep 2020 16:59:40

**US3632075**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
User entered 'I'	System	18 Sep 2020 16:59:40

US3632075

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:33:48
User entered 'Yes (Y)' reason for change: New Information	Catherine Abrams (b) (4)	25 Sep 2020 21:51:32
User entered 'No (N)' reason for change: Data Entry Error	Isaac Perez (b) (4)	21 Sep 2020 17:05:58
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	18 Sep 2020 17:52:28

US3632075

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:33:48
User entered '25 Sep 2020' reason for change: New Information	Catherine Abrams (b) (4)	25 Sep 2020 21:51:32
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	21 Sep 2020 17:05:58
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	21 Sep 2020 17:05:58
User entered empty; reason for change Data Entry Error	Isaac Perez (b) (4)	21 Sep 2020 17:05:58
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	18 Sep 2020 17:52:28
User entered '18 Sep 2020'	Sarah Wiatrek (b) (4)	18 Sep 2020 17:52:28



US3632075

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:33:48
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	Catherine Abrams (b) (4)	25 Sep 2020 21:51:32
User entered empty; reason for change Data Entry Error	Isaac Perez (b) (4)	21 Sep 2020 17:05:58
User entered 'Contact Made (CONTACT MADE)'	Sarah Wiatrek (b) (4)	18 Sep 2020 17:52:28

US3632075

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:35

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:33:48
User entered empty.	Sarah Wiatrek (b) (4)	18 Sep 2020 17:52:28

**US3632075**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:35**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:33:57
User entered 'Yes (Y)'	Catherine Abrams (b) (4)	25 Sep 2020 21:51:44

**US3632075**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
User entered 'I'	System	25 Sep 2020 21:51:44

US3632075

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:51:46
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
User entered 'Yes (Y)'	(b) (4) Bezuayehu Mandefro (b) (4)	02 Oct 2020 14:04:33

US3632075

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:51:46
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
User entered '02 Oct 2020'	(b) (4) Bezuayehu Mandefro (b) (4)	02 Oct 2020 14:04:33

US3632075

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:51:46
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Bezuayehu Mandefro (b) (4)	02 Oct 2020 14:04:33

US3632075

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:35

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:51:46
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
User entered empty.	(b) (4) Bezuayehu Mandefro (b) (4)	02 Oct 2020 14:04:33



US3632075

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:54:31
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
User entered 'Yes (Y)'	(b) (4) Bezuayehu Mandefro (b) (4)	02 Oct 2020 14:04:37

**US3632075**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
User entered 'I'	System	02 Oct 2020 14:04:37

**US3632075**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:35**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:34:37
User entered 'Yes (Y)'	Christina Bacher (b) (4)	13 Oct 2020 19:17:56

**US3632075**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:35**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:34:37
User entered '13 Oct 2020'	Christina Bacher (b) (4)	13 Oct 2020 19:17:56

US3632075

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:15:35

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:34:37
User entered 'Clinic (Clinic)'	Christina Bacher (b) (4)	13 Oct 2020 19:17:56

**US3632075**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:35**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered 'VISIT2'	System	13 Oct 2020 19:17:56

US3632075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User accepted default value 'Pre-Dose (PREDOSE)'	Christina Bacher (b) (4)	13 Oct 2020 21:22:13
	(b) (4)	

US3632075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:35:56
User entered 'Yes (Y)'	Christina Bacher (b) (4)	13 Oct 2020 21:22:13



**US3632075**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:35**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:35:56
User entered '13 Oct 2020'	Christina Bacher (b) (4)	13 Oct 2020 21:22:13

US3632075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:35:56
User entered '14:35'	Christina Bacher (b) (4)	13 Oct 2020 21:22:13

US3632075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered '13 Oct 2020 14:35'	System	13 Oct 2020 21:22:13

US3632075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:35:56
User entered '96.8' F	Christina Bacher (b) (4)	13 Oct 2020 21:22:13

US3632075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:35:56
User entered 'Oral (Oral)'	Christina Bacher (b) (4)	13 Oct 2020 21:22:13

US3632075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:35:56
User entered empty.	Christina Bacher (b) (4)	13 Oct 2020 21:22:13

**US3632075**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:35:56
User entered '79'	Christina Bacher (b) (4)	13 Oct 2020 21:22:13

**US3632075**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered 'bpm'	System	13 Oct 2020 21:22:13



US3632075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:35:56
User entered '14'	Christina Bacher (b) (4)	13 Oct 2020 21:22:13

US3632075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered 'breaths/min'	System	13 Oct 2020 21:22:13

US3632075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:35:56
User entered '111'	Christina Bacher (b) (4)	13 Oct 2020 21:22:13

US3632075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered 'mmHg'	System	13 Oct 2020 21:22:13

US3632075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:35:56
User entered '70'	Christina Bacher (b) (4)	13 Oct 2020 21:22:13

US3632075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered 'mmHg'	System	13 Oct 2020 21:22:13

US3632075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User accepted default value 'Post-Dose (POSTDOSE)'	Christina Bacher (b) (4) (b) (4)	13 Oct 2020 21:22:13

US3632075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:35:14
User entered 'Yes (Y)'	Christina Bacher (b) (4)	13 Oct 2020 21:22:13



US3632075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:35:14
User closed query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 21:26:54
User entered '13 Oct 2020' reason for change: New Information	Christina Bacher (b) (4) (b) (4)	13 Oct 2020 21:26:54
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 21:22:13
User entered empty.	Christina Bacher (b) (4) (b) (4)	13 Oct 2020 21:22:13

US3632075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:35:14
User closed query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 21:26:54
Query 'Data is required. Please provide.' answered by System data change (Site from System).		13 Oct 2020 21:26:54
User entered '17:13' reason for change: New Information	Christina Bacher (b) (4) (b) (4)	13 Oct 2020 21:26:54
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 21:22:13
User entered empty.	Christina Bacher (b) (4) (b) (4)	13 Oct 2020 21:22:13

US3632075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered '13 Oct 2020 17:13'	System	13 Oct 2020 21:26:54
User entered empty.	System	13 Oct 2020 21:22:13

US3632075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:35:14
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	15 Oct 2020 13:36:17
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 14:07:15
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	13 Oct 2020 21:26:54
User closed query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 21:26:54
Query 'Data is required. Please provide.' answered by System data change (Site from System).		13 Oct 2020 21:26:54
User entered '96.0' F reason for change: New Information	Christina Bacher (b) (4)	13 Oct 2020 21:26:54
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 21:22:13
User entered empty.	Christina Bacher (b) (4)	13 Oct 2020 21:22:13

US3632075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:35:14
User entered 'Oral (Oral)' reason for change: New Information	Christina Bacher (b) (4)	13 Oct 2020 21:26:54
User entered empty.	Christina Bacher (b) (4)	13 Oct 2020 21:22:13

US3632075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:35:14
User entered empty.	Christina Bacher (b) (4)	13 Oct 2020 21:22:13

US3632075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:35:14
User closed query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 21:26:54
Query 'Data is required. Please provide.' answered by System data change (Site from System).		13 Oct 2020 21:26:54
User entered '65' reason for change: New Information	Christina Bacher (b) (4) (b) (4)	13 Oct 2020 21:26:54
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 21:22:13
User entered empty.	Christina Bacher (b) (4) (b) (4)	13 Oct 2020 21:22:13

US3632075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered 'bpm'	System	13 Oct 2020 21:26:54
User entered empty.	System	13 Oct 2020 21:22:13



US3632075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:35:14
User closed query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 21:26:54
Query 'Data is required. Please provide.' answered by System data change (Site from System).		13 Oct 2020 21:26:54
User entered '14' reason for change: New Information	Christina Bacher (b) (4) (b) (4)	13 Oct 2020 21:26:54
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 21:22:13
User entered empty.	Christina Bacher (b) (4) (b) (4)	13 Oct 2020 21:22:13

US3632075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered 'breaths/min'	System	13 Oct 2020 21:26:54
User entered empty.	System	13 Oct 2020 21:22:13

US3632075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:35:14
User closed query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 21:26:54
Query 'Data is required. Please provide.' answered by System data change (Site from System).		13 Oct 2020 21:26:54
User entered '105' reason for change: New Information	Christina Bacher (b) (4) (b) (4)	13 Oct 2020 21:26:54
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 21:22:13
User entered empty.	Christina Bacher (b) (4) (b) (4)	13 Oct 2020 21:22:13

US3632075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered 'mmHg'	System	13 Oct 2020 21:26:54
User entered empty.	System	13 Oct 2020 21:22:13

US3632075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:35:14
User closed query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 21:26:54
Query 'Data is required. Please provide.' answered by System data change (Site from System).		13 Oct 2020 21:26:54
User entered '69' reason for change: New Information	Christina Bacher (b) (4) (b) (4)	13 Oct 2020 21:26:54
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 21:22:13
User entered empty.	Christina Bacher (b) (4) (b) (4)	13 Oct 2020 21:22:13

US3632075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered 'mmHg'	System	13 Oct 2020 21:26:54
User entered empty.	System	13 Oct 2020 21:22:13

US3632075

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:15:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:36:15
User entered 'Yes (Y)'	Christina Bacher (b) (4)	13 Oct 2020 19:18:06

US3632075

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:15:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:36:15
User entered '13 Oct 2020'	Christina Bacher (b) (4)	13 Oct 2020 19:18:06



US3632075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:35

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:36:39
User entered 'Yes (Y)'	Christina Bacher (b) (4)	13 Oct 2020 20:57:58

US3632075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:35

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:36:39
User entered empty.	Christina Bacher (b) (4)	13 Oct 2020 20:57:58

US3632075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:35

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)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:36:39
User entered empty.	Christina Bacher (b) (4)	13 Oct 2020 20:57:58

US3632075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:35

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered 'MRNA-1273 OR PLACEBO'	System	13 Oct 2020 20:57:58

US3632075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:35

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:36:39
User entered '13 Oct 2020'	Christina Bacher (b) (4)	13 Oct 2020 20:57:58

US3632075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:35

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:36:39
User entered '16:43'	Christina Bacher (b) (4)	13 Oct 2020 20:57:58

**US3632075**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:15:35**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered '13 Oct 2020 16:43'	System	13 Oct 2020 20:57:58

US3632075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:35

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:36:39
User entered 'Right Arm (RIGHT ARM)'	Christina Bacher (b) (4)	13 Oct 2020 20:57:58



US3632075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:35

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:36:39
User entered 'ONCE'	System	13 Oct 2020 20:57:58

US3632075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:35

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered 'INTRAMUSCULAR'	System	13 Oct 2020 20:57:58

US3632075

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:15:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:37:07
User entered 'Yes (Y)'	Christina Bacher (b) (4)	13 Oct 2020 19:19:16

US3632075

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:15:35

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:37:07
User entered '13 Oct 2020'	Christina Bacher (b) (4)	13 Oct 2020 19:19:16

**US3632075**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:15:35**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:37:07
User entered '15:04'	Christina Bacher (b) (4)	13 Oct 2020 19:19:16

**US3632075**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:15:35**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered '13 Oct 2020 15:04'	System	13 Oct 2020 19:19:16

**US3632075**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 09:15:35**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:37:14
User entered '13 Oct 2020'	Christina Bacher (b) (4)	13 Oct 2020 19:19:34

**US3632075**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Christina Bacher (b) (4)	13 Oct 2020 19:19:34



US3632075

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:15:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:37:14
User entered 'Yes (Y)'	Christina Bacher (b) (4)	13 Oct 2020 19:19:34

**US3632075**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:37:14
User entered '15:09'	Christina Bacher (b) (4)	13 Oct 2020 19:19:34

**US3632075**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered '13 Oct 2020 15:09'	System	13 Oct 2020 19:19:34

**US3632075**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Christina Bacher (b) (4)	13 Oct 2020 19:19:34

US3632075

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:15:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:14
User entered 'No (N)'	Christina Bacher (b) (4) (b) (4)	13 Oct 2020 19:19:34

**US3632075**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:37:14
User entered empty.	Christina Bacher (b) (4)	13 Oct 2020 19:19:34

**US3632075**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered empty.	System	13 Oct 2020 19:19:34

US3632075

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:37:28
User entered 'Yes (Y)'	Christina Bacher (b) (4)	13 Oct 2020 21:25:39



**US3632075**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered 'I'	System	13 Oct 2020 21:25:39

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	13 Oct 2020 20:57:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-13T17:18:21', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '846e276b-35bb-4ec2-badf-61bec011e628'	System	13 Oct 2020 21:18:32
User entered 'Yes (Y)'	System	13 Oct 2020 21:18:32

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-13T17:18:05', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '846e276b-35bb-4ec2-badf-61bec011e628'	System	13 Oct 2020 21:18:32
User entered '96.0'	System	13 Oct 2020 21:18:32

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-13T17:18:13', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '846e276b-35bb-4ec2-badf-61bec011e628'	System	13 Oct 2020 21:18:32
User entered 'No (N)'	System	13 Oct 2020 21:18:32

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-13T17:18:29', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '846e276b-35bb-4ec2-badf-61bec011e628'	System	13 Oct 2020 21:18:32
User entered '13 Oct 2020 17:18'	System	13 Oct 2020 21:18:32

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '13 Oct 2020 17:03'	System	13 Oct 2020 20:57:58

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '13 Oct 2020 19:33'	System	13 Oct 2020 20:57:58



US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	13 Oct 2020 20:57:58
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-13T21:25:09', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '9c57afc6-8a3a-4758-bd90-334c713595da'	System	14 Oct 2020 01:25:38
User entered 'Yes (Y)'	System	14 Oct 2020 01:25:38

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-13T21:25:21', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '9c57afc6-8a3a-4758-bd90-334c713595da'	System	14 Oct 2020 01:25:38
User entered '96.0'	System	14 Oct 2020 01:25:38

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-13T21:25:27', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '9c57afc6-8a3a-4758-bd90-334c713595da'	System	14 Oct 2020 01:25:38
User entered 'No (N)'	System	14 Oct 2020 01:25:38

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-13T21:25:35', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '9c57afc6-8a3a-4758-bd90-334c713595da'	System	14 Oct 2020 01:25:38
User entered '13 Oct 2020 21:25'	System	14 Oct 2020 01:25:38

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '13 Oct 2020 20:28'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	13 Oct 2020 20:57:58
User entered 'Day 2'	System	13 Oct 2020 20:57:58



US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:15:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-14T23:50:38', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '92ef9d76-3194-4d5e-a918-e89f84bd6e70'	System	15 Oct 2020 03:51:08
User entered 'Yes (Y)'	System	15 Oct 2020 03:51:08

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:15:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-14T23:50:50', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '92ef9d76-3194-4d5e-a918-e89f84bd6e70'	System	15 Oct 2020 03:51:08
User entered '97.8'	System	15 Oct 2020 03:51:08

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:15:35

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabb9e8d62)', Time: '2020-10-14T23:50:56', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '92ef9d76-3194-4d5e-a918-e89f84bd6e70'	System	15 Oct 2020 03:51:08
User entered 'No (N)'	System	15 Oct 2020 03:51:08

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:15:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-14T23:51:06', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '92ef9d76-3194-4d5e-a918-e89f84bd6e70'	System	15 Oct 2020 03:51:08
User entered '14 Oct 2020 23:51'	System	15 Oct 2020 03:51:08

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:15:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:15:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	13 Oct 2020 20:57:58
User entered 'Day 3'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:15:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-16T01:49:13', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'e617548d-296f-479d-b076-8c69fa07daee'	System	16 Oct 2020 05:49:46
User entered 'Yes (Y)'	System	16 Oct 2020 05:49:46



US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:15:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-16T01:49:22', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'e617548d-296f-479d-b076-8c69fa07daee'	System	16 Oct 2020 05:49:46
User entered '96.8'	System	16 Oct 2020 05:49:46

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:15:35

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-16T01:49:28', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'e617548d-296f-479d-b076-8c69fa07daee'	System	16 Oct 2020 05:49:46
User entered 'No (N)'	System	16 Oct 2020 05:49:46

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:15:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-16T01:49:40', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'e617548d-296f-479d-b076-8c69fa07daee'	System	16 Oct 2020 05:49:46
User entered '16 Oct 2020 01:49'	System	16 Oct 2020 05:49:46

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 20:57:58

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	13 Oct 2020 20:57:58
User entered 'Day 4'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:15:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-16T20:08:22', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'b38ffcf-d-2b89-4d62-a1b0-1f2fa66c5e46'	System	17 Oct 2020 00:08:54
User entered 'Yes (Y)'	System	17 Oct 2020 00:08:54

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:15:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-16T20:08:37', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'b38ffcf-d-2b89-4d62-a1b0-1f2fa66c5e46'	System	17 Oct 2020 00:08:54
User entered '95.9'	System	17 Oct 2020 00:08:54



US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:15:35

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-16T20:08:43', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'b38ffcf-d-2b89-4d62-a1b0-1f2fa66c5e46'	System	17 Oct 2020 00:08:54
User entered 'No (N)'	System	17 Oct 2020 00:08:54

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:15:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-16T20:08:51', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'b38ffcf-d-2b89-4d62-a1b0-1f2fa66c5e46'	System	17 Oct 2020 00:08:54
User entered '16 Oct 2020 20:08'	System	17 Oct 2020 00:08:54

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:15:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 20:57:58

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	13 Oct 2020 20:57:58
User entered 'Day 5'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:15:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:15:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:15:35

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53



US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:15:35

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:15:35

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:15:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 20:57:58

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	13 Oct 2020 20:57:58
User entered 'Day 6'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:15:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:15:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53



US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:15:35

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:15:35

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:15:35

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 20:57:58

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	13 Oct 2020 20:57:58
User entered 'Day 7'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:15:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-19T23:12:51', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '6b563e33-43ff-4b3d-a800-a1e3f7abd21c'	System	20 Oct 2020 03:13:25
User entered 'Yes (Y)'	System	20 Oct 2020 03:13:25



US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:15:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-19T23:13:02', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '6b563e33-43ff-4b3d-a800-a1e3f7abd21c'	System	20 Oct 2020 03:13:25
User entered '97.1'	System	20 Oct 2020 03:13:25

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:15:35

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-19T23:13:09', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '6b563e33-43ff-4b3d-a800-a1e3f7abd21c'	System	20 Oct 2020 03:13:25
User entered 'No (N)'	System	20 Oct 2020 03:13:25

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:15:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-19T23:13:20', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '6b563e33-43ff-4b3d-a800-a1e3f7abd21c'	System	20 Oct 2020 03:13:25
User entered '19 Oct 2020 23:13'	System	20 Oct 2020 03:13:25

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:15:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	13 Oct 2020 20:57:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-13T17:19:57', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '460e66ab-cf7b-444b-aa87-52fb6e20bd8e'	System	13 Oct 2020 21:21:01
User entered 'None (1)'	System	13 Oct 2020 21:21:01

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-13T17:20:25', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '460e66ab-cf7b-444b-aa87-52fb6e20bd8e'	System	13 Oct 2020 21:21:01
User entered 'No (N)'	System	13 Oct 2020 21:21:01



US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-13T17:20:29', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '460e66ab-cf7b-444b-aa87-52fb6e20bd8e'	System	13 Oct 2020 21:21:01
User entered 'No (N)'	System	13 Oct 2020 21:21:01

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-13T17:20:54', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '460e66ab-cf7b-444b-aa87-52fb6e20bd8e'	System	13 Oct 2020 21:21:01
User entered 'None (1)'	System	13 Oct 2020 21:21:01

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-13T17:20:58', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '460e66ab-cf7b-444b-aa87-52fb6e20bd8e'	System	13 Oct 2020 21:21:01
User entered '13 Oct 2020 17:20'	System	13 Oct 2020 21:21:01

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '13 Oct 2020 17:03'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '13 Oct 2020 19:33'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	13 Oct 2020 20:57:58
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-13T21:25:49', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'd7562c29-4e14-4da4-9c8d-8b97f31ef364'	System	14 Oct 2020 01:38:05
User entered 'None (1)'	System	14 Oct 2020 01:38:05

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-13T21:30:23', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'd7562c29-4e14-4da4-9c8d-8b97f31ef364'	System	14 Oct 2020 01:38:05
User entered 'No (N)'	System	14 Oct 2020 01:38:05



US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-13T21:32:44', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'd7562c29-4e14-4da4-9c8d-8b97f31ef364'	System	14 Oct 2020 01:38:05
User entered 'Yes (Y)'	System	14 Oct 2020 01:38:05

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabbf9e8d62)', Time: '2020-10-13T21:36:16', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'd7562c29-4e14-4da4-9c8d-8b97f31ef364'	System	14 Oct 2020 01:38:05
User entered '3'	System	14 Oct 2020 01:38:05

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-13T21:36:43', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'd7562c29-4e14-4da4-9c8d-8b97f31ef364'	System	14 Oct 2020 01:38:05
User entered 'None (1)'	System	14 Oct 2020 01:38:05

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-13T21:37:59', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'd7562c29-4e14-4da4-9c8d-8b97f31ef364'	System	14 Oct 2020 01:38:05
User entered '13 Oct 2020 21:37'	System	14 Oct 2020 01:38:05

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '13 Oct 2020 20:28'	System	13 Oct 2020 20:57:58

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	13 Oct 2020 20:57:58
User entered 'Day 2'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:15:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-14T23:51:28', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'c7100681-1af1-4973-ae7f-cda181f91bd9'	System	15 Oct 2020 03:54:02
User entered 'None (1)'	System	15 Oct 2020 03:54:02



US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:15:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-14T23:53:30', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'c7100681-1af1-4973-ae7f-cda181f91bd9'	System	15 Oct 2020 03:54:02
User entered 'No (N)'	System	15 Oct 2020 03:54:02

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:15:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-14T23:53:33', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'c7100681-1af1-4973-ae7f-cda181f91bd9'	System	15 Oct 2020 03:54:02
User entered 'No (N)'	System	15 Oct 2020 03:54:02

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:15:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-14T23:53:50', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'c7100681-1af1-4973-ae7f-cda181f91bd9'	System	15 Oct 2020 03:54:02
User entered 'None (1)'	System	15 Oct 2020 03:54:02

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:15:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-14T23:53:59', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'c7100681-1af1-4973-ae7f-cda181f91bd9'	System	15 Oct 2020 03:54:02
User entered '14 Oct 2020 23:53'	System	15 Oct 2020 03:54:02

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:15:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:15:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	13 Oct 2020 20:57:58
User entered 'Day 3'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:15:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-16T01:49:48', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '90344306-79cc-4c0e-89ca-b6532f4aea4c'	System	16 Oct 2020 05:50:17
User entered 'None (1)'	System	16 Oct 2020 05:50:17



US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:15:35

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-16T01:49:52', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '90344306-79cc-4c0e-89ca-b6532f4aea4c'	System	16 Oct 2020 05:50:17
User entered 'No (N)'	System	16 Oct 2020 05:50:17

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:15:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-16T01:49:57', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '90344306-79cc-4c0e-89ca-b6532f4aea4c'	System	16 Oct 2020 05:50:17
User entered 'No (N)'	System	16 Oct 2020 05:50:17

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:15:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-16T01:50:04', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '90344306-79cc-4c0e-89ca-b6532f4aea4c'	System	16 Oct 2020 05:50:17
User entered 'None (1)'	System	16 Oct 2020 05:50:17

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:15:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-16T01:50:15', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '90344306-79cc-4c0e-89ca-b6532f4aea4c'	System	16 Oct 2020 05:50:17
User entered '16 Oct 2020 01:50'	System	16 Oct 2020 05:50:17

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:15:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 20:57:58

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	13 Oct 2020 20:57:58
User entered 'Day 4'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:15:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-16T20:09:15', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '18db5974-e672-48e6-8380-c59f8e8db179'	System	17 Oct 2020 00:09:49
User entered 'None (1)'	System	17 Oct 2020 00:09:49



US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:15:35

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-16T20:09:19', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '18db5974-e672-48e6-8380-c59f8e8db179'	System	17 Oct 2020 00:09:49
User entered 'No (N)'	System	17 Oct 2020 00:09:49

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:15:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-16T20:09:25', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '18db5974-e672-48e6-8380-c59f8e8db179'	System	17 Oct 2020 00:09:49
User entered 'No (N)'	System	17 Oct 2020 00:09:49

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:15:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-16T20:09:39', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '18db5974-e672-48e6-8380-c59f8e8db179'	System	17 Oct 2020 00:09:49
User entered 'None (1)'	System	17 Oct 2020 00:09:49

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:15:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-16T20:09:46', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '18db5974-e672-48e6-8380-c59f8e8db179'	System	17 Oct 2020 00:09:49
User entered '16 Oct 2020 20:09'	System	17 Oct 2020 00:09:49

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 20:57:58

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	13 Oct 2020 20:57:58
User entered 'Day 5'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:15:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53



US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:15:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:15:35

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:15:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:15:35

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:15:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:15:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:15:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 20:57:58



US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	13 Oct 2020 20:57:58
User entered 'Day 6'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:15:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:15:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:15:35

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:15:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:15:35

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:15:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53



**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 20:57:58

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	13 Oct 2020 20:57:58
User entered 'Day 7'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:15:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-19T23:13:30', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'a5615a7b-8adf-4461-8dff-fc235554470c'	System	20 Oct 2020 03:25:44
User entered 'None (1)'	System	20 Oct 2020 03:25:44

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:15:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-19T23:24:37', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'a5615a7b-8adf-4461-8dff-fc235554470c'	System	20 Oct 2020 03:25:44
User entered 'Yes (Y)'	System	20 Oct 2020 03:25:44

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:15:35

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-19T23:25:03', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'a5615a7b-8adf-4461-8dff-fc235554470c'	System	20 Oct 2020 03:25:44
User entered '3'	System	20 Oct 2020 03:25:44

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:15:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-19T23:25:09', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'a5615a7b-8adf-4461-8dff-fc235554470c'	System	20 Oct 2020 03:25:44
User entered 'No (N)'	System	20 Oct 2020 03:25:44

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:15:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-19T23:25:24', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'a5615a7b-8adf-4461-8dff-fc235554470c'	System	20 Oct 2020 03:25:44
User entered 'None (1)'	System	20 Oct 2020 03:25:44



US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:15:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-19T23:25:40', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'a5615a7b-8adf-4461-8dff-fc235554470c'	System	20 Oct 2020 03:25:44
User entered '19 Oct 2020 23:25'	System	20 Oct 2020 03:25:44

US3632075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:15:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 20:57:58

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	13 Oct 2020 20:57:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-13T17:18:45', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'ea360632-fa17-40b1-93a0-b6f0a9b41e40'	System	13 Oct 2020 21:19:39
User entered 'None (0)'	System	13 Oct 2020 21:19:39

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-13T17:19:07', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'ea360632-fa17-40b1-93a0-b6f0a9b41e40'	System	13 Oct 2020 21:19:39
User entered 'None (0)'	System	13 Oct 2020 21:19:39

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-13T17:19:11', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'ea360632-fa17-40b1-93a0-b6f0a9b41e40'	System	13 Oct 2020 21:19:39
User entered 'None (0)'	System	13 Oct 2020 21:19:39

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-13T17:19:15', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'ea360632-fa17-40b1-93a0-b6f0a9b41e40'	System	13 Oct 2020 21:19:39
User entered 'None (0)'	System	13 Oct 2020 21:19:39



US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-13T17:19:19', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'ea360632-fa17-40b1-93a0-b6f0a9b41e40'	System	13 Oct 2020 21:19:39
User entered 'None (0)'	System	13 Oct 2020 21:19:39

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-13T17:19:23', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'ea360632-fa17-40b1-93a0-b6f0a9b41e40'	System	13 Oct 2020 21:19:39
User entered 'None (0)'	System	13 Oct 2020 21:19:39

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-13T17:19:29', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'ea360632-fa17-40b1-93a0-b6f0a9b41e40'	System	13 Oct 2020 21:19:39
User entered 'No (N)'	System	13 Oct 2020 21:19:39

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:15:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-13T17:19:36', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'ea360632-fa17-40b1-93a0-b6f0a9b41e40'	System	13 Oct 2020 21:19:39
User entered '13 Oct 2020 17:19'	System	13 Oct 2020 21:19:39

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '13 Oct 2020 17:03'	System	13 Oct 2020 20:57:58

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '13 Oct 2020 19:33'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	13 Oct 2020 20:57:58
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-13T21:38:11', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '55ce7199-9199-47ac-be73-f9b2c407372d'	System	14 Oct 2020 01:39:10
User entered 'None (0)'	System	14 Oct 2020 01:39:10



US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-13T21:38:18', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '55ce7199-9199-47ac-be73-f9b2c407372d'	System	14 Oct 2020 01:39:10
User entered 'No interference with activity (1)'	System	14 Oct 2020 01:39:10

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-13T21:38:24', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '55ce7199-9199-47ac-be73-f9b2c407372d'	System	14 Oct 2020 01:39:10
User entered 'No interference with activity (1)'	System	14 Oct 2020 01:39:10

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-13T21:38:38', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '55ce7199-9199-47ac-be73-f9b2c407372d' User entered 'None (0)'	System	14 Oct 2020 01:39:10
	System	14 Oct 2020 01:39:10

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-13T21:38:42', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '55ce7199-9199-47ac-be73-f9b2c407372d'	System	14 Oct 2020 01:39:10
User entered 'None (0)'	System	14 Oct 2020 01:39:10

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-13T21:38:46', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '55ce7199-9199-47ac-be73-f9b2c407372d'	System	14 Oct 2020 01:39:10
User entered 'None (0)'	System	14 Oct 2020 01:39:10

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabb9e8d62)', Time: '2020-10-13T21:38:51', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '55ce7199-9199-47ac-be73-f9b2c407372d'	System	14 Oct 2020 01:39:10
User entered 'No (N)'	System	14 Oct 2020 01:39:10

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:15:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-13T21:39:06', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '55ce7199-9199-47ac-be73-f9b2c407372d' User entered '13 Oct 2020 21:39'	System	14 Oct 2020 01:39:10
	System	14 Oct 2020 01:39:10

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '13 Oct 2020 20:28'	System	13 Oct 2020 20:57:58



**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	13 Oct 2020 20:57:58
User entered 'Day 2'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:15:35

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-14T23:54:20', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '97f8a946-ce28-4b2a-940a-4d0eb5a8b550'	System	15 Oct 2020 03:55:04
User entered 'None (0)'	System	15 Oct 2020 03:55:04

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:15:35

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-14T23:54:26', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '97f8a946-ce28-4b2a-940a-4d0eb5a8b550'	System	15 Oct 2020 03:55:04
User entered 'No interference with activity (1)'	System	15 Oct 2020 03:55:04

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:15:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-14T23:54:34', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '97f8a946-ce28-4b2a-940a-4d0eb5a8b550'	System	15 Oct 2020 03:55:04
User entered 'None (0)'	System	15 Oct 2020 03:55:04

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:15:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-14T23:54:38', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '97f8a946-ce28-4b2a-940a-4d0eb5a8b550'	System	15 Oct 2020 03:55:04
User entered 'None (0)'	System	15 Oct 2020 03:55:04

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:15:35

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-14T23:54:41', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '97f8a946-ce28-4b2a-940a-4d0eb5a8b550'	System	15 Oct 2020 03:55:04
User entered 'None (0)'	System	15 Oct 2020 03:55:04

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:15:35

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-14T23:54:46', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '97f8a946-ce28-4b2a-940a-4d0eb5a8b550'	System	15 Oct 2020 03:55:04
User entered 'None (0)'	System	15 Oct 2020 03:55:04



US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:15:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-14T23:54:52', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '97f8a946-ce28-4b2a-940a-4d0eb5a8b550'	System	15 Oct 2020 03:55:04
User entered 'No (N)'	System	15 Oct 2020 03:55:04

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:15:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-14T23:55:01', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '97f8a946-ce28-4b2a-940a-4d0eb5a8b550'	System	15 Oct 2020 03:55:04
User entered '14 Oct 2020 23:55'	System	15 Oct 2020 03:55:04

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 20:57:58

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	13 Oct 2020 20:57:58
User entered 'Day 3'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:15:35

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-16T01:50:27', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '9b2144b6-20d3-4604-b0b8-37bb123bf35d'	System	16 Oct 2020 05:51:14
User entered 'None (0)'	System	16 Oct 2020 05:51:14

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:15:35

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-16T01:50:33', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '9b2144b6-20d3-4604-b0b8-37bb123bf35d'	System	16 Oct 2020 05:51:14
User entered 'No interference with activity (1)'	System	16 Oct 2020 05:51:14

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:15:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-16T01:50:37', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '9b2144b6-20d3-4604-b0b8-37bb123bf35d'	System	16 Oct 2020 05:51:14
User entered 'None (0)'	System	16 Oct 2020 05:51:14



US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:15:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-16T01:50:40', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '9b2144b6-20d3-4604-b0b8-37bb123bf35d'	System	16 Oct 2020 05:51:14
User entered 'None (0)'	System	16 Oct 2020 05:51:14

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:15:35

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-16T01:50:47', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '9b2144b6-20d3-4604-b0b8-37bb123bf35d'	System	16 Oct 2020 05:51:14
User entered 'None (0)'	System	16 Oct 2020 05:51:14

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:15:35

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-16T01:50:53', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '9b2144b6-20d3-4604-b0b8-37bb123bf35d'	System	16 Oct 2020 05:51:14
User entered 'None (0)'	System	16 Oct 2020 05:51:14

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:15:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-16T01:51:00', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '9b2144b6-20d3-4604-b0b8-37bb123bf35d'	System	16 Oct 2020 05:51:14
User entered 'No (N)'	System	16 Oct 2020 05:51:14

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:15:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-16T01:51:10', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '9b2144b6-20d3-4604-b0b8-37bb123bf35d'	System	16 Oct 2020 05:51:14
User entered '16 Oct 2020 01:51'	System	16 Oct 2020 05:51:14

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 20:57:58

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 20:57:58

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	13 Oct 2020 20:57:58
User entered 'Day 4'	System	13 Oct 2020 20:57:58



US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:15:35

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-16T20:09:54', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '5cf70116-0106-4278-80c3-0ee7afbcedc8'	System	17 Oct 2020 00:10:53
User entered 'None (0)'	System	17 Oct 2020 00:10:53

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:15:35

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-16T20:09:59', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '5cf70116-0106-4278-80c3-0ee7afbcedc8'	System	17 Oct 2020 00:10:53
User entered 'No interference with activity (1)'	System	17 Oct 2020 00:10:53

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:15:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-16T20:10:03', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '5cf70116-0106-4278-80c3-0ee7afbcedc8'	System	17 Oct 2020 00:10:53
User entered 'None (0)'	System	17 Oct 2020 00:10:53

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:15:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-16T20:10:07', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '5cf70116-0106-4278-80c3-0ee7afbcedc8'	System	17 Oct 2020 00:10:53
User entered 'None (0)'	System	17 Oct 2020 00:10:53

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:15:35

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-16T20:10:16', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '5cf70116-0106-4278-80c3-0ee7afbcedc8'	System	17 Oct 2020 00:10:53
User entered 'None (0)'	System	17 Oct 2020 00:10:53

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:15:35

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-16T20:10:23', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '5cf70116-0106-4278-80c3-0ee7afbcedc8'	System	17 Oct 2020 00:10:53
User entered 'None (0)'	System	17 Oct 2020 00:10:53

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:15:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-16T20:10:37', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '5cf70116-0106-4278-80c3-0ee7afbcedc8'	System	17 Oct 2020 00:10:53
User entered 'No (N)'	System	17 Oct 2020 00:10:53

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:15:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-16T20:10:50', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '5cf70116-0106-4278-80c3-0ee7afbcedc8'	System	17 Oct 2020 00:10:53
User entered '16 Oct 2020 20:10'	System	17 Oct 2020 00:10:53



**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 20:57:58

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	13 Oct 2020 20:57:58
User entered 'Day 5'	System	13 Oct 2020 20:57:58

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:15:35**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:15:35**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:15:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:15:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:15:35**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53



**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:15:35**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:15:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 20:57:58

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	13 Oct 2020 20:57:58
User entered 'Day 6'	System	13 Oct 2020 20:57:58

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:15:35**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:15:35**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53



US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:15:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:15:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:15:35**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:15:35**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:15:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 20:57:58

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 20:57:58



US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	13 Oct 2020 20:57:58
User entered 'Day 7'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:15:35

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-19T23:25:49', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'bbdf530f-d369-447a-8400-1efe4a3e2714'	System	20 Oct 2020 03:26:22
User entered 'None (0)'	System	20 Oct 2020 03:26:22

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:15:35

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-19T23:25:53', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'bbdf530f-d369-447a-8400-1efe4a3e2714'	System	20 Oct 2020 03:26:22
User entered 'No interference with activity (1)'	System	20 Oct 2020 03:26:22

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:15:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-19T23:25:56', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'bbdf530f-d369-447a-8400-1efe4a3e2714'	System	20 Oct 2020 03:26:22
User entered 'None (0)'	System	20 Oct 2020 03:26:22

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:15:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-19T23:25:59', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'bbdf530f-d369-447a-8400-1efe4a3e2714'	System	20 Oct 2020 03:26:22
User entered 'None (0)'	System	20 Oct 2020 03:26:22

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:15:35

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-19T23:26:03', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'bbdf530f-d369-447a-8400-1efe4a3e2714'	System	20 Oct 2020 03:26:22
User entered 'None (0)'	System	20 Oct 2020 03:26:22

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:15:35

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabbf9e8d62)', Time: '2020-10-19T23:26:06', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'bbdf530f-d369-447a-8400-1efe4a3e2714'	System	20 Oct 2020 03:26:22
User entered 'None (0)'	System	20 Oct 2020 03:26:22

US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:15:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-19T23:26:11', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'bbdf530f-d369-447a-8400-1efe4a3e2714'	System	20 Oct 2020 03:26:22
User entered 'No (N)'	System	20 Oct 2020 03:26:22



US3632075

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:15:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-19T23:26:19', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'bbdf530f-d369-447a-8400-1efe4a3e2714'	System	20 Oct 2020 03:26:22
User entered '19 Oct 2020 23:26'	System	20 Oct 2020 03:26:22

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 20:57:58

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 20:57:58

US3632075

Folder: Diary Dose 2 (1)

Form: Redness\_Day(8)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	20 Oct 2020 03:25:44
User entered 'Day 8'	System	20 Oct 2020 03:25:44

US3632075

Folder: Diary Dose 2 (1)

Form: Redness\_Day(8)

Generated On: 10 Jun 2021 09:15:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

US3632075

Folder: Diary Dose 2 (1)

Form: Redness\_Day(8)

Generated On: 10 Jun 2021 09:15:35

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: Redness\_Day(8)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: Redness\_Day(8)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '20 Oct 2020 12:00'	System	20 Oct 2020 03:25:44



**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: Redness\_Day(8)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '21 Oct 2020 11:59'	System	20 Oct 2020 03:25:44

US3632075

Folder: Diary Dose 2 (1)

Form: Redness\_Day(9)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	20 Oct 2020 03:25:44
User entered 'Day 9'	System	20 Oct 2020 03:25:44

US3632075

Folder: Diary Dose 2 (1)

Form: Redness\_Day(9)

Generated On: 10 Jun 2021 09:15:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-21T23:31:57', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'b4247545-a973-431b-9327-34eab536a5b2'	System	22 Oct 2020 03:32:05
User entered 'No (N)'	System	22 Oct 2020 03:32:05

US3632075

Folder: Diary Dose 2 (1)

Form: Redness\_Day(9)

Generated On: 10 Jun 2021 09:15:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-21T23:32:02', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'b4247545-a973-431b-9327-34eab536a5b2'	System	22 Oct 2020 03:32:05
User entered '21 Oct 2020 23:32'	System	22 Oct 2020 03:32:05

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: Redness\_Day(9)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 03:25:44

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: Redness\_Day(9)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 03:25:44

US3632075

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	20 Oct 2020 03:26:22
User entered 'Day 8'	System	20 Oct 2020 03:26:22

US3632075

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 10 Jun 2021 09:15:35

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53



**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '20 Oct 2020 12:00'	System	20 Oct 2020 03:26:22

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '21 Oct 2020 11:59'	System	20 Oct 2020 03:26:22

US3632075

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	20 Oct 2020 03:26:22
User entered 'Day 9'	System	20 Oct 2020 03:26:22

US3632075

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 10 Jun 2021 09:15:35

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-21T23:32:13', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '9d615e73-ad91-4634-aa83-50e320ef463d'	System	22 Oct 2020 03:32:22
User entered 'None (0)'	System	22 Oct 2020 03:32:22

US3632075

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 10 Jun 2021 09:15:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-21T23:32:20', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '9d615e73-ad91-4634-aa83-50e320ef463d'	System	22 Oct 2020 03:32:22
User entered '21 Oct 2020 23:32'	System	22 Oct 2020 03:32:22

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 03:26:22

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 03:26:22



US3632075

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	20 Oct 2020 03:25:44
User entered 'Day 8'	System	20 Oct 2020 03:25:44

US3632075

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:15:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53

US3632075

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:15:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '20 Oct 2020 12:00'	System	20 Oct 2020 03:25:44

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '21 Oct 2020 11:59'	System	20 Oct 2020 03:25:44

US3632075

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	20 Oct 2020 03:25:44
User entered 'Day 9'	System	20 Oct 2020 03:25:44

US3632075

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 09:15:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-21T23:32:30', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'e5eb38e8-2664-4260-baee-970bd337e2db'	System	22 Oct 2020 03:32:43
User entered 'No (N)'	System	22 Oct 2020 03:32:43

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-10-21T23:32:39', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'e5eb38e8-2664-4260-baee-970bd337e2db'	System	22 Oct 2020 03:32:43
User entered '21 Oct 2020 23:32'	System	22 Oct 2020 03:32:43



**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 03:25:44

**US3632075**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 09:15:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 03:25:44

US3632075

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:37:47
User entered 'Yes (Y)'	Bezuayehu Mandefro (b) (4)	20 Oct 2020 16:24:54

US3632075

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4)	08 Jan 2021 17:37:47
User entered '20 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 16:24:54
	Bezuayehu Mandefro	
	(b) (4)	

US3632075

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4)	08 Jan 2021 17:37:47
User entered 'Contact Made (CONTACT MADE)'	Bezuayehu Mandefro	20 Oct 2020 16:24:54
	(b) (4)	

US3632075

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:35

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 17:37:47
User entered empty.	Bezuayehu Mandefro	20 Oct 2020 16:24:54
	(b) (4)	

US3632075

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4)	08 Jan 2021 17:39:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 16:24:58
	Bezuayehu Mandefro	
	(b) (4)	

**US3632075**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
User entered 'I'	System	20 Oct 2020 16:24:58



**US3632075**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:35**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:39:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 15:07:29

**US3632075**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:35**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:39:20
User entered '27 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 15:07:29

US3632075

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:39:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	27 Oct 2020 15:07:29

US3632075

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:35

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:39:20
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 15:07:29

US3632075

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:39:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 15:07:33

**US3632075**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
User entered 'I'	System	27 Oct 2020 15:07:33

US3632075

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:39:44
User entered 'Yes (Y)'	Bezuayehu Mandefro (b) (4)	03 Nov 2020 19:25:24

US3632075

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:39:44
User entered '03 Nov 2020'	Bezuayehu Mandefro (b) (4)	03 Nov 2020 19:25:24



US3632075

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4)	08 Jan 2021 17:39:44
User entered 'Contact Made (CONTACT MADE)'	Bezuayehu Mandefro	03 Nov 2020 19:25:24
	(b) (4)	

US3632075

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:35

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 17:39:44
User entered empty.	Bezuayehu Mandefro	03 Nov 2020 19:25:24
	(b) (4)	

US3632075

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4)	08 Jan 2021 17:40:28
User entered 'Yes (Y)'	Bezuayehu Mandefro	03 Nov 2020 19:25:28
	(b) (4)	

**US3632075**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
User entered 'I'	System	03 Nov 2020 19:25:28

**US3632075**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:35**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:41:36
User entered 'Yes (Y)'	Christina Bacher (b) (4)	11 Nov 2020 20:14:36

**US3632075**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:35**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:41:36
User entered '11 Nov 2020'	Christina Bacher (b) (4)	11 Nov 2020 20:14:36

**US3632075**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:35**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:41:36
User entered 'Clinic (Clinic)'	Christina Bacher (b) (4)	11 Nov 2020 20:14:36

**US3632075**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:35**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered 'VISIT3'	System	11 Nov 2020 20:14:36



US3632075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:41:44
User entered 'No (N)'	Christina Bacher (b) (4)	11 Nov 2020 20:14:47

US3632075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:41:44
User entered empty.	Christina Bacher (b) (4)	11 Nov 2020 20:14:47

**US3632075**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:35**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:41:44
User entered empty.	Christina Bacher (b) (4)	11 Nov 2020 20:14:47

US3632075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered empty.	System	11 Nov 2020 20:14:47

US3632075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:41:44
User entered empty.	Christina Bacher (b) (4)	11 Nov 2020 20:14:47

US3632075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:41:44
User entered empty.	Christina Bacher (b) (4)	11 Nov 2020 20:14:47

**US3632075**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:35**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:41:44
User entered empty.	Christina Bacher (b) (4)	11 Nov 2020 20:14:47

**US3632075**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:35**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:41:44
User entered empty.	Christina Bacher (b) (4)	11 Nov 2020 20:14:47



**US3632075**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:35**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered empty.	System	11 Nov 2020 20:14:47

US3632075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:41:44
User entered empty.	Christina Bacher (b) (4)	11 Nov 2020 20:14:47

US3632075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered empty.	System	11 Nov 2020 20:14:47

**US3632075**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:35**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:41:44
User entered empty.	Christina Bacher (b) (4)	11 Nov 2020 20:14:47

**US3632075**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:35**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered empty.	System	11 Nov 2020 20:14:47

US3632075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:41:44
User entered empty.	Christina Bacher (b) (4)	11 Nov 2020 20:14:47

US3632075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered empty.	System	11 Nov 2020 20:14:47

US3632075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:35

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14



US3632075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:35

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14

US3632075

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:15:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:41:52
User entered 'Yes (Y)'	Christina Bacher (b) (4)	11 Nov 2020 20:14:54

US3632075

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:15:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:41:52
User entered '11 Nov 2020'	Christina Bacher (b) (4)	11 Nov 2020 20:14:54

**US3632075**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:15:35**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:41:57
User entered 'Yes (Y)'	Christina Bacher (b) (4)	11 Nov 2020 20:15:06

**US3632075**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:15:35**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:41:57
User entered '11 Nov 2020'	Christina Bacher (b) (4)	11 Nov 2020 20:15:06

**US3632075**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:15:35**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:41:57
User entered '14:12'	Christina Bacher (b) (4)	11 Nov 2020 20:15:06

**US3632075**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:15:35**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered '11 Nov 2020 14:12'	System	11 Nov 2020 20:15:06

**US3632075**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:35**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:42:04
User entered 'Yes (Y)'	Christina Bacher (b) (4)	11 Nov 2020 20:15:10



**US3632075**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:14
User entered 'I'	System	11 Nov 2020 20:15:10

US3632075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	11 Sep 2020 20:25:16
User entered 'Day 64'	System	11 Sep 2020 20:25:16

US3632075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 12:09:37
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'Participant contacted nephrologist in early Nov 2020 to verify if needed to adjust dose of acyclovir for his ongoing shingles. Dosage was not adjusted. ' (Site from DM).	Sarah Wiatrek (b) (4) (b) (4)	15 Feb 2021 15:45:38
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	19 Dec 2020 11:07:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-11-15T05:55:53', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '5b0aa88f-c91c-4e9f-9650-460647ee05bc'	System	15 Nov 2020 10:57:07
User entered 'Yes (Y)'	System	15 Nov 2020 10:57:07

US3632075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-11-15T05:56:00', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '5b0aa88f-c91c-4e9f-9650-460647ee05bc'	System	15 Nov 2020 10:57:07
User entered 'No (N)'	System	15 Nov 2020 10:57:07

US3632075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

[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)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-11-15T05:56:05', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '5b0aa88f-c91c-4e9f-9650-460647ee05bc'	System	15 Nov 2020 10:57:07
User entered 'No (N)'	System	15 Nov 2020 10:57:07

US3632075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

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)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-11-15T05:56:15', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '5b0aa88f-c91c-4e9f-9650-460647ee05bc'	System	15 Nov 2020 10:57:07
User entered 'Yes (Y)'	System	15 Nov 2020 10:57:07

**US3632075**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Please 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)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-11-15T05:56:39', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '5b0aa88f-c91c-4e9f-9650-460647ee05bc'	System	15 Nov 2020 10:57:07
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Nov 2020 10:57:07

**US3632075**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabb9e8d62)', Time: '2020-11-15T05:56:57', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '5b0aa88f-c91c-4e9f-9650-460647ee05bc'	System	15 Nov 2020 10:57:07
User entered '15 Nov 2020 05:56:57'	System	15 Nov 2020 10:57:07



**US3632075**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	11 Sep 2020 20:25:16
User entered '11 Nov 2020 00:01'	System	11 Sep 2020 20:25:16

**US3632075**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:53
Data entry locked.	System	11 Sep 2020 20:25:16
User entered '15 Nov 2020 23:59'	System	11 Sep 2020 20:25:16

**US3632075**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:36:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:44:25
Data entry locked.	System	11 Sep 2020 20:25:16
User entered 'Day 71'	System	11 Sep 2020 20:25:16

US3632075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

[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)	24 Apr 2021 03:36:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:44:25

US3632075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

Have you been exposed to someone with 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)	24 Apr 2021 03:36:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Please 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)	24 Apr 2021 03:36:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:44:25

US3632075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

[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)	24 Apr 2021 03:36:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:36:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:36:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:36:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:36:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:36:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:36:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:36:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:36:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:44:25

US3632075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:36:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:36:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:36:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:36:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:36:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:36:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:36:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:36:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:36:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Please 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)	24 Apr 2021 03:36:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:44:25

US3632075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:35

[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)	24 Apr 2021 03:36:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

Please 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)	24 Apr 2021 03:36:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:36:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:36:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:44:25
Data entry locked.	System	11 Sep 2020 20:25:16
User entered '18 Nov 2020 00:01'	System	11 Sep 2020 20:25:16

**US3632075**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:36:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:44:25
Data entry locked.	System	11 Sep 2020 20:25:16
User entered '22 Nov 2020 23:59'	System	11 Sep 2020 20:25:16

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[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 (e1d0c9aabb9e8d62)', Time: '2020-11-22T13:43:25', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '0b61c076-34e1-43b2-ba05-22aa45a7d7cb'	System	22 Nov 2020 18:43:44
User entered 'No (N)'	System	22 Nov 2020 18:43:44



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

Have you been exposed to someone with 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 (e1d0c9aabb9e8d62)', Time: '2020-11-22T13:43:32', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '0b61c076-34e1-43b2-ba05-22aa45a7d7cb'	System	22 Nov 2020 18:43:44
User entered 'No (N)'	System	22 Nov 2020 18:43:44

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-11-22T13:43:41', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '0b61c076-34e1-43b2-ba05-22aa45a7d7cb' User entered '22 Nov 2020 13:43:41'	System	22 Nov 2020 18:43:44

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[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 (e1d0c9aabf9e8d62)', Time: '2020-11-29T23:41:53', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'ac04f800-7d57-4d00-ba3d-90aa2d29632d'	System	30 Nov 2020 04:42:15
User entered 'No (N)'	System	30 Nov 2020 04:42:15

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

Have you been exposed to someone with 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 (e1d0c9aabf9e8d62)', Time: '2020-11-29T23:41:59', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'ac04f800-7d57-4d00-ba3d-90aa2d29632d'	System	30 Nov 2020 04:42:15
User entered 'No (N)'	System	30 Nov 2020 04:42:15

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-11-29T23:42:09', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'ac04f800-7d57-4d00-ba3d-90aa2d29632d'	System	30 Nov 2020 04:42:15
User entered '29 Nov 2020 23:42:09'	System	30 Nov 2020 04:42:15



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[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 (e1d0c9aabb9e8d62)', Time: '2020-12-08T09:43:20', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '93db4827-a70b-4415-a848-cf180e24c80c'	System	08 Dec 2020 14:43:40
User entered 'No (N)'	System	08 Dec 2020 14:43:40

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

Have you been exposed to someone with 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 (e1d0c9aabf9e8d62)', Time: '2020-12-08T09:43:26', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '93db4827-a70b-4415-a848-cf180e24c80c'	System	08 Dec 2020 14:43:40
User entered 'No (N)'	System	08 Dec 2020 14:43:40

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2020-12-08T09:43:35', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '93db4827-a70b-4415-a848-cf180e24c80c'	System	08 Dec 2020 14:43:40
User entered '08 Dec 2020 09:43:35'	System	08 Dec 2020 14:43:40

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[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 (e1d0c9aabf9e8d62)', Time: '2021-01-04T23:11:59', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'b6d40d40-267f-4021-8118-6fc6b2e688fb'	System	05 Jan 2021 04:12:15
User entered 'No (N)'	System	05 Jan 2021 04:12:15

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

Have you been exposed to someone with 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 (e1d0c9aabf9e8d62)', Time: '2021-01-04T23:12:04', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'b6d40d40-267f-4021-8118-6fc6b2e688fb'	System	05 Jan 2021 04:12:15
User entered 'No (N)'	System	05 Jan 2021 04:12:15

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2021-01-04T23:12:10', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: 'b6d40d40-267f-4021-8118-6fc6b2e688fb' User entered '04 Jan 2021 23:12:10'	System	05 Jan 2021 04:12:15

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[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 (e1d0c9aabb9e8d62)', Time: '2021-01-14T10:15:41', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '7677dc21-4d96-41cb-99b3-5c52370a48b0'	System	14 Jan 2021 15:15:55
User entered 'No (N)'	System	14 Jan 2021 15:15:55

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Have you been exposed to someone with 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 (e1d0c9aabf9e8d62)', Time: '2021-01-14T10:15:46', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '7677dc21-4d96-41cb-99b3-5c52370a48b0'	System	14 Jan 2021 15:15:55
User entered 'No (N)'	System	14 Jan 2021 15:15:55

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2021-01-14T10:15:52', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '7677dc21-4d96-41cb-99b3-5c52370a48b0'	System	14 Jan 2021 15:15:55
User entered '14 Jan 2021 10:15:52'	System	14 Jan 2021 15:15:55

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[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 (e1d0c9aabf9e8d62)', Time: '2021-01-19T14:07:21', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '73dc88c2-df53-4a39-84db-51830452ae68'	System	19 Jan 2021 19:07:44
User entered 'No (N)'	System	19 Jan 2021 19:07:44

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

Have you been exposed to someone with 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 (e1d0c9aabf9e8d62)', Time: '2021-01-19T14:07:26', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '73dc88c2-df53-4a39-84db-51830452ae68'	System	19 Jan 2021 19:07:44
User entered 'No (N)'	System	19 Jan 2021 19:07:44



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2021-01-19T14:07:40', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '73dc88c2-df53-4a39-84db-51830452ae68' User entered '19 Jan 2021 14:07:40'	System	19 Jan 2021 19:07:44
	System	19 Jan 2021 19:07:44

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[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 (e1d0c9aabf9e8d62)', Time: '2021-02-04T12:36:14', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '36d712e0-8d57-4219-8422-d1b43344773d'	System	04 Feb 2021 17:36:31
User entered 'No (N)'	System	04 Feb 2021 17:36:31



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

Have you been exposed to someone with 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 (e1d0c9aabf9e8d62)', Time: '2021-02-04T12:36:19', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '36d712e0-8d57-4219-8422-d1b43344773d'	System	04 Feb 2021 17:36:31
User entered 'No (N)'	System	04 Feb 2021 17:36:31

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d0c9aabf9e8d62)', Time: '2021-02-04T12:36:26', User OID: 'PatientReportedOutcome (US3632075)', ODM File OID: '36d712e0-8d57-4219-8422-d1b43344773d'	System	04 Feb 2021 17:36:31
User entered '04 Feb 2021 12:36:26'	System	04 Feb 2021 17:36:31

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 07:44:25



**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:44:25
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 07:44:25

**US3632075**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:35**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:42:45
User entered 'Yes (Y)'	Aastha KC (b) (4)	08 Dec 2020 14:39:42

**US3632075**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:35**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:42:45
User entered '8 Dec 2020'	Aastha KC (b) (4)	08 Dec 2020 14:39:42

**US3632075**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:35**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:42:45
User entered 'Contact Made (CONTACT MADE)'	Aastha KC (b) (4)	08 Dec 2020 14:39:42

US3632075

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:35

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:42:45
User entered empty.	Aastha KC (b) (4)	08 Dec 2020 14:39:42

**US3632075**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:35**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:42:54
User entered 'Yes (Y)'	Aastha KC (b) (4)	08 Dec 2020 14:39:48



**US3632075**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:48:08
User entered 'I'	System	08 Dec 2020 14:39:48

US3632075

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:38:11
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:56:44
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	08 Feb 2021 20:52:33
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	08 Feb 2021 20:51:25
User entered 'No (N)'	Sarah Wiatrek (b) (4) (b) (4)	08 Feb 2021 20:51:25

US3632075

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:38:11
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	25 Mar 2021 14:56:44
User closed query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	08 Feb 2021 20:52:33
Query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered by data change (Site from System).	System	08 Feb 2021 20:52:33
User closed query 'The 'Date of Contact or Contact Attempt' is before the 'Date of Informed Consent'. Please review and reconcile.' (Site from System).	System	08 Feb 2021 20:52:33
User entered empty; reason for change Data Entry Error	Sarah Wiatrek (b) (4)	08 Feb 2021 20:52:33
User opened query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	08 Feb 2021 20:51:56
User opened query 'The 'Date of Contact or Contact Attempt' is before the 'Date of Informed Consent'. Please review and reconcile.' (Site from System).	System	08 Feb 2021 20:51:56
User entered '11 Jan 2020' reason for change: Data Entry Error	Sarah Wiatrek (b) (4)	08 Feb 2021 20:51:56
User entered empty.	Sarah Wiatrek (b) (4)	08 Feb 2021 20:51:25

**US3632075**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:35**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:38:11
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:56:44
User entered empty; reason for change Data Entry Error	Sarah Wiatrek (b) (4)	08 Feb 2021 20:52:33
User entered 'Contact Not Made (CONTACT NOT MADE)'	Sarah Wiatrek (b) (4)	08 Feb 2021 20:51:25

US3632075

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:35

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:38:11
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:56:44
User entered 'Safety call was missed due to OL visit'	Sarah Wiatrek (b) (4)	08 Feb 2021 20:51:25

**US3632075**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:35**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:38:11
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:58:16
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	08 Feb 2021 20:52:50

**US3632075**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:38:11
User entered 'I'	System	08 Feb 2021 20:52:50

**US3632075**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:35**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:38:11
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:56:42
User entered 'Yes (Y)'	Aastha KC (b) (4)	11 Feb 2021 20:46:14



**US3632075**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:35**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:38:11
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:56:42
User entered '11 Feb 2021'	Aastha KC (b) (4)	11 Feb 2021 20:46:14

**US3632075**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:35**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:38:11
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:56:42
User entered 'Contact Made (CONTACT MADE)'	Aastha KC (b) (4)	11 Feb 2021 20:46:14

US3632075

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:35

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:38:11
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:56:42
User entered empty.	Aastha KC (b) (4)	11 Feb 2021 20:46:14

**US3632075**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:35**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:38:11
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:56:46
User entered 'Yes (Y)'	Aastha KC (b) (4)	11 Feb 2021 20:46:16

**US3632075**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:38:11
User entered 'I'	System	11 Feb 2021 20:46:16

**US3632075**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:35**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:38:11
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:57:06
User entered 'Yes (Y)'	Isaac Perez (b) (4)	12 Mar 2021 19:51:38

**US3632075**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:35**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:38:11
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:57:06
User entered '12 Mar 2021'	Isaac Perez (b) (4)	12 Mar 2021 19:51:38

**US3632075**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:35**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:38:11
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:57:06
User entered 'Contact Made (CONTACT MADE)'	Isaac Perez (b) (4)	12 Mar 2021 19:51:38



US3632075

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:35

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:38:11
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:57:06
User entered empty.	Isaac Perez (b) (4)	12 Mar 2021 19:51:38

**US3632075**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:35**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:38:11
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:57:12
User entered 'Yes (Y)'	Isaac Perez (b) (4)	12 Mar 2021 19:51:43

**US3632075**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:38:11
User entered 'I'	System	12 Mar 2021 19:51:43

US3632075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:15:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:03:52
User entered 'Yes (Y)'	Christina Bacher (b) (4)	04 Jan 2021 21:19:52

**US3632075**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:35**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:03:52
User entered '4 Jan 2021'	Christina Bacher (b) (4)	04 Jan 2021 21:19:52

**US3632075**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:35**

[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 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:03:52
User entered 'Clinic (Clinic)'	Christina Bacher (b) (4)	04 Jan 2021 21:19:52

**US3632075**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:35**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered 'UNBLND_DECIDE'	System	04 Jan 2021 21:19:52

US3632075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:15:35

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:04:09
User entered '4 Jan 2021'	Christina Bacher (b) (4)	04 Jan 2021 21:20:08



**US3632075**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:15:35**

[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 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:10:08
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 12:22:09
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:53:34

**US3632075**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:15:35**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:04:09
User entered 'Yes (Y)'	Christina Bacher (b) (4)	04 Jan 2021 21:20:08

US3632075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:15:35

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User closed query 'Per CDA, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 15:52:43
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:10:08
Query 'Per CDA, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 12:22:14
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	09 Apr 2021 12:22:09
User opened query 'Per CDA, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 20:15:11
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:53:34

US3632075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:15:35

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:04:09
User entered '4 Jan 2021'	Christina Bacher (b) (4)	04 Jan 2021 21:20:08

US3632075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:15:35

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:04:09
User entered 'Placebo (Placebo)'	Christina Bacher (b) (4)	04 Jan 2021 21:20:08

**US3632075**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:15:35**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:04:09
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 09:24:20
User entered 'Placebo (Placebo)'	Christina Bacher (b) (4) (b) (4)	04 Jan 2021 21:20:08

**US3632075**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:15:35**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:04:09
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 09:24:20
User entered 'Placebo (Placebo)'	Christina Bacher (b) (4) (b) (4)	04 Jan 2021 21:20:08

US3632075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:15:35

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:04:09
User entered 'Yes (Y)'	Christina Bacher (b) (4)	04 Jan 2021 21:20:08



**US3632075**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:15:35**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered '1'	System	04 Jan 2021 21:20:08

**US3632075**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:15:35**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered 'I'	System	04 Jan 2021 21:20:08

US3632075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:15:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:04:55
User entered '64.5' in	Christina Bacher (b) (4)	04 Jan 2021 21:24:05

US3632075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:15:35

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:04:58
User entered '192.6' lb	Christina Bacher (b) (4)	04 Jan 2021 21:24:05

US3632075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:15:35

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered '32.61720'	System	04 Jan 2021 21:24:05
DataPoint set to visible.	System	04 Jan 2021 21:20:08

US3632075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:15:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:04:55
User entered '64.5' in	Christina Bacher (b) (4)	04 Jan 2021 21:24:05

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:15:35

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:04:58
User entered '192.6' lb	Christina Bacher (b) (4)	04 Jan 2021 21:24:05

**US3632075**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:15:35**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered '32.61720'	System	04 Jan 2021 21:24:05
DataPoint set to visible.	System	04 Jan 2021 21:20:08



US3632075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User accepted default value 'Pre-Dose (PREDOSE)'	Christina Bacher (b) (4) (b) (4)	04 Jan 2021 21:24:05

US3632075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:05:02
User entered 'Yes (Y)'	Christina Bacher (b) (4)	04 Jan 2021 21:24:05

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:05:02
User entered '4 Jan 2021'	Christina Bacher (b) (4)	04 Jan 2021 21:24:05

**US3632075**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:05:02
User entered '14:27'	Christina Bacher (b) (4)	04 Jan 2021 21:24:05

**US3632075**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered '4 Jan 2021 14:27'	System	04 Jan 2021 21:24:05

US3632075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:05:02
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	12 Jan 2021 03:15:08
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4), (b) (6)	11 Jan 2021 18:04:58
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	04 Jan 2021 21:24:05
User entered '96' F	Christina Bacher (b) (4)	04 Jan 2021 21:24:05

US3632075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:05:02
User entered 'Oral (Oral)'	Christina Bacher (b) (4)	04 Jan 2021 21:24:05

US3632075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:05:02
User entered empty.	Christina Bacher (b) (4)	04 Jan 2021 21:24:05



**US3632075**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:05:02
User entered '77'	Christina Bacher (b) (4)	04 Jan 2021 21:24:05

**US3632075**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered 'bpm'	System	04 Jan 2021 21:24:05

US3632075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:05:02
User entered '14'	Christina Bacher (b) (4)	04 Jan 2021 21:24:05

US3632075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered 'breaths/min'	System	04 Jan 2021 21:24:05

US3632075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:05:02
User entered '126'	Christina Bacher (b) (4)	04 Jan 2021 21:24:05

**US3632075**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered 'mmHg'	System	04 Jan 2021 21:24:05

US3632075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:05:02
User entered '74'	Christina Bacher (b) (4)	04 Jan 2021 21:24:05

**US3632075**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered 'mmHg'	System	04 Jan 2021 21:24:05



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:15:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:04:55
User entered '64.5' in	Christina Bacher (b) (4)	04 Jan 2021 21:24:05

US3632075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:15:35

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:04:58
User entered '192.6' lb	Christina Bacher (b) (4)	04 Jan 2021 21:24:05

US3632075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:15:35

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered '32.61720'	System	04 Jan 2021 21:24:05
DataPoint set to visible.	System	04 Jan 2021 21:20:08

US3632075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User accepted default value 'Post-Dose (POSTDOSE)'	Christina Bacher (b) (4) (b) (4)	04 Jan 2021 21:24:05

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:07:15
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Jan 2021 21:42:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Jan 2021 21:42:26
User entered 'Yes (Y)' reason for change: New Information	Christina Bacher (b) (4) (b) (4)	04 Jan 2021 21:42:26
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Jan 2021 21:24:05
User entered empty.	Christina Bacher (b) (4) (b) (4)	04 Jan 2021 21:24:05

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:07:15
User entered '4 Jan 2021' reason for change: New Information	Christina Bacher (b) (4)	04 Jan 2021 21:42:26
User entered empty.	Christina Bacher (b) (4)	04 Jan 2021 21:24:05

**US3632075**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:07:15
User entered '16:35' reason for change: New Information	Christina Bacher (b) (4)	04 Jan 2021 21:42:26
User entered empty.	(b) (4) Christina Bacher (b) (4) (b) (4)	04 Jan 2021 21:24:05

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered '4 Jan 2021 16:35'	System	04 Jan 2021 21:42:26
User entered empty.	System	04 Jan 2021 21:24:05



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:07:15
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	12 Jan 2021 03:15:19
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4), (b) (6)	11 Jan 2021 18:05:30
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	04 Jan 2021 21:42:26
User entered '95.6' F reason for change: New Information	Christina Bacher (b) (4)	04 Jan 2021 21:42:26
User entered empty.	Christina Bacher (b) (4)	04 Jan 2021 21:24:05

US3632075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:07:15
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Jan 2021 18:05:34
Query 'Data is required. Please provide.' answered by System data change (Site from System).		11 Jan 2021 18:05:34
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 18:05:34
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Jan 2021 21:42:26
User entered empty.	Christina Bacher (b) (4)	04 Jan 2021 21:24:05

**US3632075**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:35**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:07:15
User entered empty.	Christina Bacher (b) (4)	04 Jan 2021 21:24:05

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 15:07:15
User entered '77' reason for change: New Information	Christina Bacher (b) (4)	04 Jan 2021 21:42:26
User entered empty.	(b) (4)	
	Christina Bacher (b) (4)	04 Jan 2021 21:24:05
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered 'bpm'	System	04 Jan 2021 21:42:26
User entered empty.	System	04 Jan 2021 21:24:05

US3632075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 15:07:15
User entered '16' reason for change: New Information	Christina Bacher (b) (4)	04 Jan 2021 21:42:26
User entered empty.	(b) (4)	
	Christina Bacher (b) (4)	04 Jan 2021 21:24:05
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered 'breaths/min'	System	04 Jan 2021 21:42:26
User entered empty.	System	04 Jan 2021 21:24:05

US3632075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 15:07:15
User entered '138' reason for change: New Information	Christina Bacher (b) (4)	04 Jan 2021 21:42:26
User entered empty.	(b) (4)	
	Christina Bacher (b) (4)	04 Jan 2021 21:24:05
	(b) (4)	



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered 'mmHg'	System	04 Jan 2021 21:42:26
User entered empty.	System	04 Jan 2021 21:24:05

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 15:07:15
User entered '79' reason for change: New Information	Christina Bacher (b) (4)	04 Jan 2021 21:42:26
User entered empty.	(b) (4)	
	Christina Bacher (b) (4)	04 Jan 2021 21:24:05
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered 'mmHg'	System	04 Jan 2021 21:42:26
User entered empty.	System	04 Jan 2021 21:24:05

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:15:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:07:57
User entered 'Yes (Y)'	Christina Bacher (b) (4)	04 Jan 2021 21:24:15

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:15:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:07:57
User entered '4 Jan 2021'	Christina Bacher (b) (4)	04 Jan 2021 21:24:15

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:35

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:26:07
User entered 'Yes (Y)'	Christina Bacher (b) (4)	04 Jan 2021 21:24:43

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:35

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:26:07
User entered empty.	Christina Bacher (b) (4)	04 Jan 2021 21:24:43

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:35

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:26:07
User entered empty.	Christina Bacher (b) (4)	04 Jan 2021 21:24:43



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:35

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered 'mRNA-1273'	System	04 Jan 2021 21:24:43
DataPoint set to visible.	System	04 Jan 2021 21:20:08

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:35

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:26:07
User entered '4 Jan 2021'	Christina Bacher (b) (4)	04 Jan 2021 21:24:43

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:35

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:26:07
User entered '16:02'	Christina Bacher (b) (4)	04 Jan 2021 21:24:43

**US3632075**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:15:35**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered '4 Jan 2021 16:02'	System	04 Jan 2021 21:24:43

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:35

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:26:07
User entered 'Right Arm (RIGHT ARM)'	Christina Bacher (b) (4)	04 Jan 2021 21:24:43

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:35

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:26:07
User entered 'ONCE'	System	04 Jan 2021 21:24:43

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:35

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered 'INTRAMUSCULAR'	System	04 Jan 2021 21:24:43

US3632075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:15:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:26:24
User entered 'Yes (Y)'	Christina Bacher (b) (4)	04 Jan 2021 21:20:30



US3632075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:15:35

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:26:24
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 04JAN2020 for the Participant Decision Visit, however, the Collection Date recorded here is 04JAN2021. Please confirm the correct Collection Date in the query response and update if appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 22:56:16
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 04JAN2020 for the Participant Decision Visit, however, the Collection Date recorded here is 04JAN2021. Please confirm the correct Collection Date in the query response and update if appropriate. ' answered with 'The date is 04JAN2021' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 16:28:17
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 04JAN2020 for the Participant Decision Visit, however, the Collection Date recorded here is 04JAN2021. Please confirm the correct Collection Date in the query response and update if appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 22:15:57
User entered '4 Jan 2021'	Christina Bacher (b) (4)	04 Jan 2021 21:20:30

**US3632075**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:15:35**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:26:24
User entered '14:45'	Christina Bacher (b) (4)	04 Jan 2021 21:20:30

**US3632075**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:15:35**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered '4 Jan 2021 14:45'	System	04 Jan 2021 21:20:30

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:15:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:27:37
User entered 'Yes (Y)'	Christina Bacher (b) (4) (b) (4)	04 Jan 2021 21:20:45

US3632075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:15:35

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:27:37
User entered '4 Jan 2021'	Christina Bacher (b) (4)	04 Jan 2021 21:20:45

US3632075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:15:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:27:37
User entered '14:48'	Christina Bacher (b) (4)	04 Jan 2021 21:20:45

**US3632075**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:15:35**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered '4 Jan 2021 14:48'	System	04 Jan 2021 21:20:45

US3632075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:27:42
User entered 'Yes (Y)'	Christina Bacher (b) (4)	04 Jan 2021 21:20:59



**US3632075**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered 'I'	System	04 Jan 2021 21:20:59

**US3632075**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:35**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:31:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Jan 2021 21:32:49

**US3632075**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:35**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:31:58
User entered '11 Jan 2021'	(b) (4), (b) (6)	11 Jan 2021 21:32:49

**US3632075**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:35**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:31:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Jan 2021 21:32:49

**US3632075**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:35**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:31:58
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 21:32:49

**US3632075**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:35**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:32:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Jan 2021 21:32:57

**US3632075**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered 'I'	System	11 Jan 2021 21:32:57

**US3632075**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:35**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered '1'	System	11 Jan 2021 21:32:57
DataPoint set to visible.	System	11 Jan 2021 21:32:57



**US3632075**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:35**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:33:26
User entered 'Yes (Y)'	Isaac Perez (b) (4)	04 Feb 2021 16:07:38

**US3632075**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:35**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:33:26
User entered '4 Feb 2021'	Isaac Perez (b) (4)	04 Feb 2021 16:07:38

**US3632075**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:35**

[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 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:33:26
User entered 'Clinic (Clinic)'	Isaac Perez (b) (4)	04 Feb 2021 16:07:38

**US3632075**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:35**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered 'OLD29'	System	04 Feb 2021 16:07:38

**US3632075**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User accepted default value 'Pre-Dose (PREDOSE)'	Isaac Perez (b) (4) (b) (4)	04 Feb 2021 18:35:47

US3632075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:38:28
User entered 'Yes (Y)'	Isaac Perez (b) (4)	04 Feb 2021 18:35:47

**US3632075**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:38:28
User entered '4 Feb 2021'	Isaac Perez (b) (4)	04 Feb 2021 18:35:47

**US3632075**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:38:28
User entered '10:11'	Isaac Perez (b) (4)	04 Feb 2021 18:35:47



**US3632075**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered '4 Feb 2021 10:11'	System	04 Feb 2021 18:35:47

US3632075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:38:28
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	08 Feb 2021 06:19:11
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4), (b) (6)	05 Feb 2021 19:30:16
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	04 Feb 2021 18:35:47
User entered '96.5' F	Isaac Perez (b) (4)	04 Feb 2021 18:35:47

**US3632075**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:38:28
User entered 'Oral (Oral)'	Isaac Perez (b) (4)	04 Feb 2021 18:35:47

**US3632075**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:35**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:38:28
User entered empty.	Isaac Perez (b) (4)	04 Feb 2021 18:35:47

**US3632075**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:38:28
User entered '77'	Isaac Perez (b) (4)	04 Feb 2021 18:35:47

**US3632075**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered 'bpm'	System	04 Feb 2021 18:35:47

US3632075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:38:28
User entered '15'	Isaac Perez (b) (4)	04 Feb 2021 18:35:47

US3632075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered 'breaths/min'	System	04 Feb 2021 18:35:47



**US3632075**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:38:28
User entered '133'	Isaac Perez (b) (4)	04 Feb 2021 18:35:47

**US3632075**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered 'mmHg'	System	04 Feb 2021 18:35:47

**US3632075**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:38:28
User entered '79'	Isaac Perez (b) (4)	04 Feb 2021 18:35:47

**US3632075**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered 'mmHg'	System	04 Feb 2021 18:35:47

US3632075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User accepted default value 'Post-Dose (POSTDOSE)'	Isaac Perez (b) (4) (b) (4)	04 Feb 2021 18:35:47

US3632075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:55:14
User entered 'Yes (Y)'	Isaac Perez (b) (4)	04 Feb 2021 18:35:47

**US3632075**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:35**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:55:14
User entered '4 Feb 2021'	Isaac Perez (b) (4)	04 Feb 2021 18:35:47

**US3632075**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:55:14
User entered '12:38'	Isaac Perez (b) (4)	04 Feb 2021 18:35:47



US3632075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered '4 Feb 2021 12:38'	System	04 Feb 2021 18:35:47

US3632075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:55:14
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	08 Feb 2021 06:19:34
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4), (b) (6)	05 Feb 2021 19:30:26
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	04 Feb 2021 18:35:47
User entered '96.0' F	Isaac Perez (b) (4)	04 Feb 2021 18:35:47

US3632075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:55:14
User entered 'Oral (Oral)'	Isaac Perez (b) (4)	04 Feb 2021 18:35:47

**US3632075**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:35**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:55:14
User entered empty.	Isaac Perez (b) (4)	04 Feb 2021 18:35:47

**US3632075**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:55:14
User entered '75'	Isaac Perez (b) (4)	04 Feb 2021 18:35:47

**US3632075**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered 'bpm'	System	04 Feb 2021 18:35:47

US3632075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:55:14
User entered '16'	Isaac Perez (b) (4)	04 Feb 2021 18:35:47

US3632075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered 'breaths/min'	System	04 Feb 2021 18:35:47



US3632075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:35

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:55:14
User entered '123'	Isaac Perez (b) (4)	04 Feb 2021 18:35:47

**US3632075**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered 'mmHg'	System	04 Feb 2021 18:35:47

**US3632075**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:55:14
User entered '70'	Isaac Perez (b) (4)	04 Feb 2021 18:35:47

**US3632075**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered 'mmHg'	System	04 Feb 2021 18:35:47

US3632075

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:15:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:55:22
User entered 'Yes (Y)'	Isaac Perez (b) (4)	04 Feb 2021 16:07:49

**US3632075**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:15:35**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:55:22
User entered '4 Feb 2021'	Isaac Perez (b) (4)	04 Feb 2021 16:07:49

**US3632075**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:15:35**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:55:28
User entered 'Yes (Y)'	Isaac Perez (b) (4)	04 Feb 2021 18:36:25

**US3632075**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:15:35**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:55:28
User entered empty.	Isaac Perez (b) (4)	04 Feb 2021 18:36:25



US3632075

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:35

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:55:28
User entered empty.	Isaac Perez (b) (4)	04 Feb 2021 18:36:25

**US3632075**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:15:35**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered 'mRNA-1273'	System	04 Feb 2021 18:36:25
DataPoint set to visible.	System	11 Jan 2021 21:32:57

US3632075

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:35

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:55:28
User entered '4 Feb 2021'	Isaac Perez (b) (4)	04 Feb 2021 18:36:25

**US3632075**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:15:35**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:55:28
User entered '12:05'	Isaac Perez (b) (4)	04 Feb 2021 18:36:25

**US3632075**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:15:35**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered '4 Feb 2021 12:05'	System	04 Feb 2021 18:36:25

**US3632075**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:15:35**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:55:28
User entered 'Right Arm (RIGHT ARM)'	Isaac Perez (b) (4)	04 Feb 2021 18:36:25

US3632075

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:35

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:55:28
User entered 'ONCE'	System	04 Feb 2021 18:36:25

US3632075

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:35

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered 'INTRAMUSCULAR'	System	04 Feb 2021 18:36:25



**US3632075**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:35**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:55:37
User entered 'Yes (Y)'	Isaac Perez (b) (4)	04 Feb 2021 16:07:56

**US3632075**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered 'I'	System	04 Feb 2021 16:07:56

**US3632075**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:35**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:56:21
User entered 'Yes (Y)'	Aastha KC (b) (4)	12 Feb 2021 16:43:39

**US3632075**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:35**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:56:21
User entered '11 Feb 2021'	Aastha KC (b) (4)	12 Feb 2021 16:43:39

**US3632075**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:35**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:56:21
User entered 'Contact Made (CONTACT MADE)'	Aastha KC (b) (4)	12 Feb 2021 16:43:39

**US3632075**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:35**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:56:21
User entered empty.	Aastha KC (b) (4)	12 Feb 2021 16:43:39

**US3632075**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:35**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:56:27
User entered 'Yes (Y)'	Aastha KC (b) (4)	12 Feb 2021 16:43:44

**US3632075**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:27
User entered 'I'	System	12 Feb 2021 16:43:44



**US3632075**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:35**

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:18:46
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
User entered 'No (N)'	(b) (4)	30 Mar 2021 18:54:03
	(b) (4), (b) (6)	

**US3632075**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:35**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:18:46
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
User entered empty.	(b) (4)	30 Mar 2021 18:54:03
	(b) (4), (b) (6)	

**US3632075**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:35**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:18:46
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
User entered empty.	(b) (4)	30 Mar 2021 18:54:03
	(b) (4), (b) (6)	

**US3632075**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:35**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	30 Mar 2021 18:54:03

**US3632075**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:35**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:18:58
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
User entered 'No (N)'	(b) (4)	30 Mar 2021 18:54:09
	(b) (4), (b) (6)	

**US3632075**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:35**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:18:58
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
User entered empty.	(b) (4)	30 Mar 2021 18:54:09
	(b) (4), (b) (6)	

**US3632075**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:35**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:18:58
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
User entered empty.	(b) (4)	30 Mar 2021 18:54:09
	(b) (4), (b) (6)	

**US3632075**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:35**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 18:54:09



**US3632075**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:35**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:18:58
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
User entered empty.	(b) (4)	30 Mar 2021 18:54:09
	(b) (4), (b) (6)	

**US3632075**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:35**

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:18:58
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
User entered empty.	(b) (4)	30 Mar 2021 18:54:09
	(b) (4), (b) (6)	

**US3632075**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:35**

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:18:58
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
User entered empty.	(b) (4)	30 Mar 2021 18:54:09
	(b) (4), (b) (6)	

**US3632075**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:35**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:18:58
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
User entered empty.	(b) (4)	30 Mar 2021 18:54:09
	(b) (4), (b) (6)	

**US3632075**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:35**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 18:54:09

US3632075

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:18:58
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
User entered empty.	(b) (4)	30 Mar 2021 18:54:09
	(b) (4), (b) (6)	

**US3632075**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:35**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 18:54:09

**US3632075**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:35**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:18:58
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
User entered empty.	(b) (4)	30 Mar 2021 18:54:09
	(b) (4), (b) (6)	



**US3632075**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:35**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 18:54:09

**US3632075**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:35**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:18:58
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
User entered empty.	(b) (4)	30 Mar 2021 18:54:09
	(b) (4), (b) (6)	

**US3632075**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:35**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 18:54:09

US3632075

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:15:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:19:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
User entered 'No (N)'	(b) (4)	30 Mar 2021 18:54:22
	(b) (4), (b) (6)	

**US3632075**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:15:35**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:19:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
User entered empty.	(b) (4)	30 Mar 2021 18:54:22
	(b) (4), (b) (6)	

**US3632075**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:15:35**

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:19:18
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
User entered 'No (N)'	(b) (4)	30 Mar 2021 18:54:51
	(b) (4), (b) (6)	

US3632075

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:15:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:19:18
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
User entered empty.	(b) (4)	30 Mar 2021 18:54:51
	(b) (4), (b) (6)	

**US3632075**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:15:35**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:19:18
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
User entered empty.	(b) (4)	30 Mar 2021 18:54:51
	(b) (4), (b) (6)	



**US3632075**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:15:35**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 18:54:51

**US3632075**

**Folder: Unscheduled 10 Nov 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 10 Jun 2021 09:15:35**

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:30:24
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:01:00
User entered '10 Nov 2020'	Aastha KC (b) (4)	03 Dec 2020 16:22:43

US3632075

Folder: Unscheduled 10 Nov 2020

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 09:15:35

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:30:24
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:01:00
User closed query 'Per CDM:As per CCGs pages 14-15, safety call is not added in unscheduled assessments, instead add it in safety call if an unscheduled call is made. Please review and reconcile or else provide clarification. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 09:59:37
Query 'Per CDM:As per CCGs pages 14-15, safety call is not added in unscheduled assessments, instead add it in safety call if an unscheduled call is made. Please review and reconcile or else provide clarification. Thank you.' answered with 'This was an unscheduled phone call conducted to make contact with the participant due to the protocol.' (Site from DM).	Aastha KC (b) (4) (b) (4)	08 Dec 2020 14:24:29
User opened query 'Per CDM:As per CCGs pages 14-15, safety call is not added in unscheduled assessments, instead add it in safety call if an unscheduled call is made. Please review and reconcile or else provide clarification. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 05:24:26
User closed query 'Procedure(s) performed is missing. Please check at least one procedure from the options provided.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 05:24:12
Query 'Procedure(s) performed is missing. Please check at least one procedure from the options provided.' answered with 'THIS WAS AN UNSCHEDULED SAFETY CALL AS REQUIRED BY THE MONITOR.' (Site from DM).	Kelly Likos (b) (4) (b) (4)	04 Dec 2020 15:39:01
User opened query 'Procedure(s) performed is missing. Please check at least one procedure from the options provided.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 03:14:18
Query 'Procedure(s) performed is missing. Please check at least one procedure from the options provided.' canceled (Site from System).	(b) (4), (b) (6)	04 Dec 2020 03:14:12

US3632075

Folder: Unscheduled 10 Nov 2020

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 09:15:35

[Physical Exam](#)

Audit	User	Time (GMT)
User opened query 'Procedure(s) performed is missing. Please check at least one procedure from the options provided.' (Site from System).	System	03 Dec 2020 16:22:43
User entered '0'	Aastha KC (b) (4) (b) (4)	03 Dec 2020 16:22:43

**US3632075**

**Folder: Unscheduled 10 Nov 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 10 Jun 2021 09:15:35**

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:30:24
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:01:00
User entered '0'	Aastha KC (b) (4)	03 Dec 2020 16:22:43

**US3632075**

**Folder: Unscheduled 10 Nov 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 10 Jun 2021 09:15:35**

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:30:24
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:01:00
User entered '0'	Aastha KC (b) (4)	03 Dec 2020 16:22:43

**US3632075**

**Folder: Unscheduled 10 Nov 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 10 Jun 2021 09:15:35**

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:30:24
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:01:00
User entered '0'	Aastha KC (b) (4)	03 Dec 2020 16:22:43

US3632075

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:15:35

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:04:21
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:00:23
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:26:16
User entered 'Yes (Y)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:33:56



**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:35**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:15

US3632075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:35

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:15
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User coded data point as SOC: Gastrointestinal disorders, HLT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 13:37:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 13:37:38
Data point term sent to Coder	System	19 Oct 2020 13:36:19
User entered 'Diarrhea'	Sarah Wiatrek (b) (4)	19 Oct 2020 13:35:28

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:15
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'No (N)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:35:28

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:15
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'No (N)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:35:28

US3632075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:15
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'No (N)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:35:28

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:15
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '15 Oct 2020'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:35:28

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:15
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty.	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:35:28

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:35**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:15
User entered empty.	System	19 Oct 2020 13:35:28



**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:15
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'No (N)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:35:28

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:35**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:15
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '16 Oct 2020'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:35:28

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:35**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:15
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty.	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:35:28

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:35**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:15
User entered empty.	System	19 Oct 2020 13:35:28

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:15
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Sarah Wiatrek (b) (4)	19 Oct 2020 13:35:28

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:15
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'No (N)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:35:28

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:15
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:35:28

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:15
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:35:28



**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:15
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:35:28

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:35**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:15
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty.	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:35:28

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:35**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:15
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty.	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:35:28

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:15
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty.	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:35:28

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:15
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty.	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:35:28

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:15
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:35:28

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:15
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:35:28

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:15
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:35:28



**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:15
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'Not Related (NOT RELATED)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:35:28

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:15
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'Related (RELATED)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:35:28

US3632075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:35

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:15
User closed query 'Per CDM: Per CCGs, if the Adverse event started during a time period when study dose was not given, "Not applicable" should be selected for "Action taken with investigational product". Please review and update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 09:45:32
Query 'Per CDM: Per CCGs, if the Adverse event started during a time period when study dose was not given, "Not applicable" should be selected for "Action taken with investigational product". Please review and update as appropriate, else clarify.'	(b) (4), (b) (6)	06 Apr 2021 17:19:04
answered with 'This was reported within 7 days of receiving second dose of IP' (Site from DM).		
User opened query 'Per CDM: Per CCGs, if the Adverse event started during a time period when study dose was not given, "Not applicable" should be selected for "Action taken with investigational product". Please review and update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 07:41:31
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'None (NONE)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:35:28

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:35**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:15
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:35:28

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:15
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'I'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:35:28

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:15
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:35:28

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:15
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:35:28

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:35**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:15
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty.	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:35:28



**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:15
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty.	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:35:28

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:15
User entered '0'	System	19 Oct 2020 13:35:28

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:15
User entered '0'	System	19 Oct 2020 13:35:28

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:15

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:35**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:37

US3632075

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:35

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:37
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	27 Oct 2020 15:16:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 15:16:47
Data point term sent to Coder	System	27 Oct 2020 15:16:00
User entered 'Diarrhea'	(b) (4), (b) (6)	27 Oct 2020 15:15:07

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:37
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 15:15:07

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:37
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 15:15:07



US3632075

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:37
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:15:07

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:37
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:15:07

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:37
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 15:15:07

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:35**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:37
User entered empty.	System	27 Oct 2020 15:15:07

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:37
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 15:15:07

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:35**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:37
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:15:07

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:35**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:37
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty.	(b) (4)	27 Oct 2020 15:15:07
	(b) (4), (b) (6)	

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:35**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:37
User entered empty.	System	27 Oct 2020 15:15:07



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:35

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:37
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:15:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:37
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 15:15:07

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:37
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 15:15:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:35

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:37
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 15:15:07

US3632075

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:37
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	27 Oct 2020 15:15:34
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	27 Oct 2020 15:15:34
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	27 Oct 2020 15:15:07
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 15:15:07

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:35**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:37
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 15:15:07

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:35**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:37
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 15:15:07

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:37
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 15:15:34
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 15:15:07



**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:37
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty.	(b) (4)	27 Oct 2020 15:15:07
	(b) (4), (b) (6)	

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:37
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 15:15:07

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:37
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 15:15:07

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:37
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 15:15:07

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:37
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:15:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:35

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:37
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:15:07

US3632075

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:35

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:37
User signature succeeded.	Colleen Kelley (b) (4)	28 Apr 2021 22:19:03
DataPoint Verified.	(b) (4)	21 Apr 2021 20:40:28
Signature has been broken.	Christina Bacher (b) (4)	20 Apr 2021 19:56:27
User entered 'None (NONE)' reason for change:	Christina Bacher (b) (4)	20 Apr 2021 19:56:27
Data Entry Error	(b) (4)	
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User closed query 'Per CDM: Per CCGs, if the Adverse event started during a time period when study dose was not given, "Not applicable" should be selected for "Action taken with investigational product". Please review and update as appropriate, else clarify.' (Site from DM).	(b) (4)	07 Apr 2021 09:45:49
Query 'Per CDM: Per CCGs, if the Adverse event started during a time period when study dose was not given, "Not applicable" should be selected for "Action taken with investigational product". Please review and update as appropriate, else clarify.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 17:17:49
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 17:17:34
Signature has been broken.	(b) (4), (b) (6)	06 Apr 2021 17:17:34
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 17:17:34
User opened query 'Per CDM: Per CCGs, if the Adverse event started during a time period when study dose was not given, "Not applicable" should be selected for "Action taken with investigational product". Please review and update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 07:41:44
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:35

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	(b) (4), (b) (6)	27 Oct 2020 15:15:07



**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:35**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:37
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 15:15:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:35

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:37
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:10:16
' (Site from DM). Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	Sarah Wiatrek (b) (4) (b) (4)	15 Feb 2021 15:37:06
' answered with 'Medication has been added. ' (Site from DM). User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	(b) (4), (b) (6)	03 Jan 2021 10:16:42
' (Site from DM). User entered 'I'	(b) (4), (b) (6)	27 Oct 2020 15:15:07

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:37
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 15:15:07

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:37
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:15:07

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:35**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:37
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty.	(b) (4)	27 Oct 2020 15:15:07
	(b) (4), (b) (6)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:37
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 15:15:07

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:37
User entered '0'	System	27 Oct 2020 15:15:07

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:37
User entered '0'	System	27 Oct 2020 15:15:07



**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:37
User entered '0'	System	27 Oct 2020 15:15:07

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:15:35

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User coded data point as SOC: Vascular disorders, HLT: Lymphatic vessel disorders, HLT: Lymphoedemas, PT: Lymphoedema, LLT: Lymphedema - version MedDRA\23.0.	Coder Import (b) (4)	24 Feb 2021 15:22:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Feb 2021 15:22:58
Data point term sent to Coder	System	11 Feb 2021 21:52:47
User entered 'Worsening of Lymphedema of Leg'	Aastha KC (b) (4)	11 Feb 2021 21:52:15

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:15:35**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'Yes (Y)'	Aastha KC (b) (4)	11 Feb 2021 21:52:15

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:15:35**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'No (N)'	Aastha KC (b) (4)	11 Feb 2021 21:52:15

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:15:35**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'No (N)'	Aastha KC (b) (4)	11 Feb 2021 21:52:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:15:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Feb 2021 21:05:07
User entered '29 Jan 2021' reason for change: Data Entry Error	Aastha KC (b) (4)	12 Feb 2021 21:05:07
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Feb 2021 21:01:59
User entered 'Jan 2021' (non-conformant).	Aastha KC (b) (4)	12 Feb 2021 21:01:59
User closed query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	12 Feb 2021 21:01:48
User closed query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify.' (Site from System).	System	12 Feb 2021 21:01:48
User entered '20 Jan 2021' reason for change: Data Entry Error	Aastha KC (b) (4)	12 Feb 2021 21:01:48
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	12 Feb 2021 16:51:39
User opened query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify.' (Site from System).	System	12 Feb 2021 16:51:39
User closed query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	12 Feb 2021 16:51:39

US3632075

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:15:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	12 Feb 2021 16:51:39
User entered '20 Jan 2020' reason for change: Data Entry Error	Aastha KC (b) (4)	12 Feb 2021 16:51:39
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	12 Feb 2021 16:50:04
User opened query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	12 Feb 2021 16:50:04
User closed query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	12 Feb 2021 16:50:04
User closed query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	12 Feb 2021 16:50:04
User entered '18 Jan 2020' reason for change: Data Entry Error	Aastha KC (b) (4)	12 Feb 2021 16:50:04
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	12 Feb 2021 16:49:44

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:15:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'The Start Date for Adverse Event System is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	12 Feb 2021 16:49:44
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Feb 2021 16:49:44
User entered '01 Jan 2020' reason for change: Data Entry Error	Aastha KC (b) (4)	12 Feb 2021 16:49:44
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Feb 2021 16:49:27
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Feb 2021 16:49:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Feb 2021 16:49:27
User entered ' Jan 2020' (non-conformant).	Aastha KC (b) (4)	12 Feb 2021 16:49:27
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Feb 2021 21:52:15
User entered empty.	Aastha KC (b) (4)	11 Feb 2021 21:52:15



**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:15:35**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty.	Aastha KC (b) (4)	11 Feb 2021 21:52:15

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:15:35**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Feb 2021 21:52:15

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:15:35**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'Yes (Y)'	Aastha KC (b) (4)	11 Feb 2021 21:52:15

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Folder: Adverse Events

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If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty.	Aastha KC (b) (4)	11 Feb 2021 21:52:15

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty.	Aastha KC (b) (4)	11 Feb 2021 21:52:15

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Feb 2021 21:52:15

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Folder: Adverse Events

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	12 Feb 2021 16:49:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Feb 2021 16:49:27
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Aastha KC (b) (4)	12 Feb 2021 16:49:27
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Feb 2021 21:52:15
User entered empty.	System	11 Feb 2021 21:52:15
	Aastha KC (b) (4)	11 Feb 2021 21:52:15
	(b) (4)	

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	12 Feb 2021 16:49:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Feb 2021 16:49:27
User entered 'No (N)' reason for change: Data Entry Error	Aastha KC (b) (4)	12 Feb 2021 16:49:27
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Feb 2021 21:52:15
User entered empty.	System	11 Feb 2021 21:52:15
	Aastha KC (b) (4)	11 Feb 2021 21:52:15
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	Aastha KC (b) (4)	11 Feb 2021 21:52:15

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:15:35**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	Aastha KC (b) (4)	11 Feb 2021 21:52:15

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:15:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	Aastha KC (b) (4)	11 Feb 2021 21:52:15

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty.	Aastha KC (b) (4)	11 Feb 2021 21:52:15

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty.	Aastha KC (b) (4)	11 Feb 2021 21:52:15

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty.	Aastha KC (b) (4)	11 Feb 2021 21:52:15

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty.	Aastha KC (b) (4)	11 Feb 2021 21:52:15

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	Aastha KC (b) (4)	11 Feb 2021 21:52:15



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	Aastha KC (b) (4)	11 Feb 2021 21:52:15

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Form: Adverse Events (3)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	Aastha KC (b) (4)	11 Feb 2021 21:52:15

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 23:25:11
User closed query 'Please confirm if this is related to study drug; per the source, related is answered "no".' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 23:25:00
Query 'Please confirm if this is related to study drug; per the source, related is answered "no".' answered with 'updated' (Site from CRA).	Bezuayehu Mandefro (b) (4)	26 Mar 2021 12:48:39
Signature has been broken.	Bezuayehu Mandefro (b) (4)	26 Mar 2021 12:47:31
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Bezuayehu Mandefro (b) (4)	26 Mar 2021 12:47:31
User opened query 'Please confirm if this is related to study drug; per the source, related is answered "no".' (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 16:12:23
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 16:10:58
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User closed query 'Per CDM: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product should be reported as "Related" or "Not Related". Please consider updating the CRF accordingly.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 10:38:53
Query 'Per CDM: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product should be reported as "Related" or "Not Related". Please consider updating the CRF accordingly.' answered with 'Updated selection' (Site from DM).	Isaac Perez (b) (4)	15 Mar 2021 17:02:19
User entered 'Related (RELATED)' reason for change: Data Entry Error	Isaac Perez (b) (4)	15 Mar 2021 17:02:12

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Form: Adverse Events (3)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product should be reported as "Related" or "Not Related". Please consider updating the CRF accordingly.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 05:52:05
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Feb 2021 16:49:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Feb 2021 16:49:53
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Aastha KC (b) (4)	12 Feb 2021 16:49:53
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Feb 2021 21:52:15
User entered empty.	Aastha KC (b) (4)	11 Feb 2021 21:52:15

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	12 Feb 2021 16:49:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Feb 2021 16:49:53
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Aastha KC (b) (4)	12 Feb 2021 16:49:53
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Feb 2021 21:52:15
User entered empty.	System	11 Feb 2021 21:52:15
	Aastha KC (b) (4)	11 Feb 2021 21:52:15
	(b) (4)	

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Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Feb 2021 21:03:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Feb 2021 21:03:30
User entered 'None (NONE)' reason for change: Data Entry Error	Aastha KC (b) (4)	12 Feb 2021 21:03:30
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Feb 2021 21:52:15
User entered empty.	Aastha KC (b) (4)	11 Feb 2021 21:52:15

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None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	12 Feb 2021 21:03:30
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	11 Feb 2021 21:52:15
User entered '0'	Aastha KC (b) (4) (b) (4)	11 Feb 2021 21:52:15

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '1' reason for change: Data Entry Error	(b) (4) Aastha KC (b) (4)	12 Feb 2021 21:03:30
User entered '0'	(b) (4) Aastha KC (b) (4)	11 Feb 2021 21:52:15



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:15:35**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	Aastha KC (b) (4)	11 Feb 2021 21:52:15

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Feb 2021 21:03:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Feb 2021 21:03:30
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Aastha KC (b) (4)	12 Feb 2021 21:03:30
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Feb 2021 21:52:15
User entered empty.	Aastha KC (b) (4)	11 Feb 2021 21:52:15
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:15:35**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty.	Aastha KC (b) (4)	11 Feb 2021 21:52:15

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Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'Patient went to cardiologist for WORSENING OF LYMPHEDEMA OF LEG and his dosage of Lasix was increased to 40 mg. This is updated in CON-Meds' reason for change: Data Entry Error	Aastha KC (b) (4)	12 Feb 2021 21:03:30
User entered empty.	Aastha KC (b) (4)	11 Feb 2021 21:52:15

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:15:35**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Feb 2021 16:49:27

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:15:35**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Feb 2021 21:52:15

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:15:35**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 16:39:49
User entered		
'USA-US120-2021-mRNA-1273-P301000004'	System	23 Feb 2021 16:39:43
User entered 'New'	(b) (4), (b) (6)	23 Feb 2021 16:39:43

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:15:35

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4)	22 Feb 2021 20:26:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Feb 2021 20:26:01
Data point term sent to Coder	System	22 Feb 2021 20:25:28
User entered 'Myocardial Infarction'	(b) (4), (b) (6)	22 Feb 2021 20:24:51



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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:15:35**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 20:24:51

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:15:35**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'No (N)'	(b) (4), (b) (6)	22 Feb 2021 20:24:51

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:15:35**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'No (N)'	(b) (4), (b) (6)	22 Feb 2021 20:24:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:15:35

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:24:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:15:35

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4)	22 Feb 2021 20:25:25
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 20:25:25
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	22 Feb 2021 20:24:51
User entered '08:00'	(b) (4), (b) (6)	22 Feb 2021 20:24:51

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:15:35**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 20:25:25
User entered '12 Feb 2021 08:00'	System	22 Feb 2021 20:24:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:15:35

[Ongoing?](#)

Audit	User	Time (GMT)
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 DM).	(b) (4), (b) (6)	27 Apr 2021 16:46:03
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 'end date recorded in EDC at 03Mar2021' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 13:31:38
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 DM).	(b) (4), (b) (6)	23 Apr 2021 18:03:43
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4) System	15 Mar 2021 17:43:37
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 17:43:37
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	15 Mar 2021 17:43:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 20:24:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:15:35

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	15 Mar 2021 17:43:16
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	15 Mar 2021 17:43:16
User entered '03 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 17:43:16
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	15 Mar 2021 17:34:51
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 20:24:51



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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:15:35**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 20:24:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:15:35

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 00:17:48
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 14:24:35
User entered empty.	System	22 Feb 2021 20:24:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:15:35

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 23:28:45
User closed query 'Potentially life threatening is checked in the source; please verify and update EDC. (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 23:28:29
Query 'Potentially life threatening is checked in the source; please verify and update EDC.' answered with 'updated' (Site from CRA).	Bezuayehu Mandefro (b) (4)	26 Mar 2021 12:50:16
Signature has been broken.	Bezuayehu Mandefro (b) (4)	26 Mar 2021 12:49:59
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Bezuayehu Mandefro (b) (4)	26 Mar 2021 12:49:59
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 20:07:11
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:07:03
User opened query 'Potentially life threatening is checked in the source; please verify and update EDC. (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 16:58:28
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 16:15:55
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4)	
	(b) (4), (b) (6)	22 Feb 2021 20:24:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:15:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 20:24:51

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:15:35**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	(b) (4), (b) (6)	22 Feb 2021 20:24:51

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:15:35**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'I'	(b) (4), (b) (6)	22 Feb 2021 20:24:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:15:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	16 Mar 2021 10:37:28
User closed query 'Per CDM:Kindly consider to enter hospital discharge date or admitted to ICU after data is being received.Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 10:37:20
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'discharge date added. No admission to ICU.' (Site from System).	(b) (4), (b) (6)	15 Mar 2021 17:36:16
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	15 Mar 2021 17:34:51
Query 'Per CDM:Kindly consider to enter hospital discharge date or admitted to ICU after data is being received.Thank you.' answered with 'added' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 17:32:03
User opened query 'Per CDM:Kindly consider to enter hospital discharge date or admitted to ICU after data is being received.Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 03:40:43
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	24 Feb 2021 03:39:11
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'subject remains hospitalized currently' (Site from System).	(b) (4), (b) (6)	22 Feb 2021 20:26:10

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:15:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). User entered 'I'	System	22 Feb 2021 20:24:51
	(b) (4), (b) (6)	22 Feb 2021 20:24:51



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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:15:35**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '12 Feb 2021'	(b) (4), (b) (6)	22 Feb 2021 20:24:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:15:35

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 13:23:12
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'discharge date added' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 17:36:53
User entered '03 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 17:34:51
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 23:11:45
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 20:24:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:15:35

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 21:27:28
User closed query 'Please update the source with this information.' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 21:27:25
Query 'Please update the source with this information.' answered with 'updated' (Site from CRA).	Christina Bacher (b) (4)	22 Apr 2021 20:18:21
User opened query 'Please update the source with this information.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 20:47:51
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User closed query 'Per CDM RQ: Response to a previous query indicates "No admission to ICU". Per CCGs, this field is to be completed with Yes, No, or Unknown and not left empty. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 09:46:34
Query 'Per CDM RQ: Response to a previous query indicates "No admission to ICU". Per CCGs, this field is to be completed with Yes, No, or Unknown and not left empty. Please update accordingly.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 14:50:19
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	05 Apr 2021 14:50:04
Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).	System	05 Apr 2021 14:50:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 14:50:04
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	05 Apr 2021 14:49:27
DataPoint Un-verified.	(b) (4), (b) (6)	05 Apr 2021 14:49:27
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 14:49:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:15:35

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'Unknown (UNK)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 14:49:27
User opened query 'Per CDM RQ: Response to a previous query indicates "No admission to ICU". Per CCGs, this field is to be completed with Yes, No, or Unknown and not left empty. Please update accordingly. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 10:46:19
User signature succeeded.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System). Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System). User entered empty; reason for change Data Entry Error	Colleen Kelley (b) (4) (b) (4) System	22 Mar 2021 18:21:37 22 Feb 2021 20:25:25 22 Feb 2021 20:25:25
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System). User entered 'Unknown (UNK)'	(b) (4), (b) (6)	22 Feb 2021 20:24:51 22 Feb 2021 20:24:51

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**Form: Adverse Events (4)**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 20:24:51

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'I'	(b) (4), (b) (6)	22 Feb 2021 20:24:51

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:15:35**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	(b) (4), (b) (6)	22 Feb 2021 20:24:51

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:15:35**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	(b) (4), (b) (6)	22 Feb 2021 20:24:51



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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:15:35**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:24:51

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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:15:35

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:24:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:15:35

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	28 Apr 2021 22:19:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:42:21
DataPoint Un-verified.	Christina Bacher (b) (4)	20 Apr 2021 19:57:17
	(b) (4)	
Signature has been broken.	Christina Bacher (b) (4)	20 Apr 2021 19:57:17
	(b) (4)	
User entered 'None (NONE)' reason for change:	Christina Bacher (b) (4)	20 Apr 2021 19:57:17
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	22 Feb 2021 20:24:51

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	(b) (4), (b) (6)	22 Feb 2021 20:24:51

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Folder: Adverse Events

Form: Adverse Events (4)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Con med, coumadin, starting in 2015 was removed. Please confirm if that is no longer con med.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 14:48:22
Query 'PV Query: Con med, coumadin, starting in 2015 was removed. Please confirm if that is no longer con med.' answered with 'Coumadin is still being taken as seen in different entries seen in the con med log' (Site from Safety).	Isaac Perez (b) (4) (b) (4)	05 Apr 2021 19:42:57
User opened query 'PV Query: Con med, coumadin, starting in 2015 was removed. Please confirm if that is no longer con med.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 18:37:30
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	22 Mar 2021 18:21:37
User entered 'I'	(b) (4), (b) (6)	22 Feb 2021 20:24:51

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:15:35**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'I'	(b) (4), (b) (6)	22 Feb 2021 20:24:51

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Folder: Adverse Events

Form: Adverse Events (4)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 13:23:17
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 17:37:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4), (b) (6)	15 Mar 2021 17:34:51
Data Entry Error		
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 23:13:10
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	22 Feb 2021 20:24:51

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 13:23:21
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 17:37:15
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 14:25:42
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 20:24:51



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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User closed query 'Per DM CLR: Narrative indicates that subject has had "PCI." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 15:29:07
User closed query 'PV Query: Please provide hospital discharge summary, any relevant laboratory and diagnostic test results. 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).	(b) (4), (b) (6)	16 Mar 2021 13:23:46
User closed query 'PV Query: Please provide any additional treatment given for the events 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)	16 Mar 2021 13:23:29
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 13:23:26
Query 'PV Query: Please provide any additional treatment given for the events 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 'No further treatment done for this particular AE' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 17:42:54

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:15:35

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative indicates that subject has had "PCI." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' answered with 'PCI not done, removed from narrative' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 17:37:32
Query 'PV Query: Please provide hospital discharge summary, any relevant laboratory and diagnostic test results. 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 'Will forward' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 17:37:23
User entered 'PARTICIPANT WAS ADMITTED TO HOSPITAL (EMORY CLIFTON) VIA EMS ON 2/12 FOR MYOCARDIAL INFARCTION. UNDERWENT Right Heart CARDIAC CATHETERIZATION. Troponin downtrended, no further cardiac intervention was given for MI' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 17:34:51
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'covid tested by PCR on 2/13 and negative' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 17:33:08
User opened query 'Per DM CLR: Narrative indicates that subject has had "PCI." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 07:16:07
User opened query 'PV Query: Please provide hospital discharge summary, any relevant laboratory and diagnostic test results. 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).	(b) (4), (b) (6)	02 Mar 2021 23:14:20

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:15:35

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the hospital discharge date when available.' canceled (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 23:14:09
User opened query 'PV Query: Please provide any additional treatment given for the events 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)	02 Mar 2021 23:13:42
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 23:09:57
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 23:09:15
User entered 'PARTICIPANT WAS ADMITTED TO HOSPITAL (Emory Clifton) VIA EMS ON 2/12 FOR MYOCARDIAL INFARCTION. UNDERWENT CARDIAC CATHETERIZATION WITH PCI AND REMAINS IN HOSPITAL IN CRITICAL CONDITION WITH SUBSEQUENT PERSISTENT HEART FAILURE (EF APPROX 20% PER WIFE'S REPORT WHO IS ALSO A PHYSICIAN). IS CURRENTLY UNDERGOING AGGRESSIVE DIURESIS WITH CONTINUOUS LASIX DRIP.' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 20:27:11
User entered 'Participant was admitted to hospital via EMS on 2/12 for myocardial infarction. Underwent cardiac catheterization with PCI and remains in hospital in critical condition with subsequent persistent heart failure (EF approx 20% per wife's report who is also a physician). Is currently undergoing aggressive diuresis with continuous lasix drip.'	(b) (4), (b) (6)	22 Feb 2021 20:24:51

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Feb 2021 20:24:51

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Feb 2021 20:24:51

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Feb 2021 20:24:51

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:15:35**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
Reviewed for Safety.	(b) (4)	25 Feb 2021 19:18:10
User entered 'USA-US120-2021-mRNA-1273-P301000004'	(b) (4), (b) (6)	25 Feb 2021 19:18:03

US3632075

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:15:35

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:46:45
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 17:21:30
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User coded data point as SOC: Renal and urinary disorders, HLT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Renal failure, LLT: Renal failure aggravated - version MedDRA\\23.0.	Coder Import (b) (4)	25 Feb 2021 19:07:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Feb 2021 19:07:00
Data point term sent to Coder	System	24 Feb 2021 18:59:38
User entered 'Worsening Renal Failure'	(b) (4), (b) (6)	24 Feb 2021 18:59:11



**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:15:35**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 18:59:11

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:15:35**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'No (N)'	(b) (4), (b) (6)	24 Feb 2021 18:59:11

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:15:35**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'No (N)'	(b) (4), (b) (6)	24 Feb 2021 18:59:11

US3632075

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:15:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '14 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:59:11

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:15:35**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 18:59:11

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:15:35**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 18:59:11

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:15:35

[Ongoing?](#)

Audit	User	Time (GMT)
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 DM).	(b) (4), (b) (6)	27 Apr 2021 16:46:19
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 'end date noted in source and EDC at 03Mar2021' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 13:33:04
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 DM).	(b) (4), (b) (6)	23 Apr 2021 18:05:47
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 17:49:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 18:59:11

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:15:35

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	15 Mar 2021 17:49:05
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	15 Mar 2021 17:49:05
User entered '03 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 17:49:05
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	15 Mar 2021 17:45:12
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 18:59:11



**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:15:35**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 18:59:11

US3632075

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:15:35

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 00:18:16
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 14:15:44
User entered empty.	System	24 Feb 2021 18:59:11

US3632075

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:15:35

Severity

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	28 Apr 2021 22:19:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 21:27:47
User closed query 'Life threatening is noted on the source; please verify and update EDC.' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 21:27:43
Query 'Life threatening is noted on the source; please verify and update EDC.' answered with 'updated' (Site from CRA).	Christina Bacher (b) (4)	22 Apr 2021 20:21:08
Signature has been broken.	(b) (4)	
	Christina Bacher (b) (4)	22 Apr 2021 20:20:15
	(b) (4)	
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Christina Bacher (b) (4)	22 Apr 2021 20:20:15
	(b) (4)	
User opened query 'Life threatening is noted on the source; please verify and update EDC.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 20:49:25
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 15:47:01
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	24 Feb 2021 18:59:11

US3632075

Folder: Adverse Events

Form: Adverse Events (5)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 18:59:11

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:15:35**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	(b) (4), (b) (6)	24 Feb 2021 18:59:11

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:15:35**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '1' reason for change: New Information	(b) (4), (b) (6)	24 Feb 2021 19:01:45
User entered '0'	(b) (4), (b) (6)	24 Feb 2021 18:59:11

US3632075

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:15:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	26 Feb 2021 09:48:19
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'has not yet been discharged from hospital' (Site from System).	(b) (4), (b) (6)	24 Feb 2021 18:59:31
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	24 Feb 2021 18:59:11
User entered 'I'	(b) (4), (b) (6)	24 Feb 2021 18:59:11

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:15:35**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '12 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 18:59:11



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Folder: Adverse Events

Form: Adverse Events (5)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 13:24:10
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 17:49:35
User entered '03 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 17:45:12
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 14:15:23
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 18:59:11

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'No (N)'	(b) (4), (b) (6)	24 Feb 2021 18:59:11

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 18:59:11

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Folder: Adverse Events

Form: Adverse Events (5)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	(b) (4), (b) (6)	24 Feb 2021 18:59:11

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	(b) (4), (b) (6)	24 Feb 2021 18:59:11

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'I'	(b) (4), (b) (6)	24 Feb 2021 18:59:11

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	24 Feb 2021 18:59:11

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	24 Feb 2021 18:59:11



**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	28 Apr 2021 22:19:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 21:28:29
DataPoint Un-verified.	Christina Bacher (b) (4)	20 Apr 2021 19:57:38
	(b) (4)	
Signature has been broken.	Christina Bacher (b) (4)	20 Apr 2021 19:57:38
	(b) (4)	
User entered 'None (NONE)' reason for change:	Christina Bacher (b) (4)	20 Apr 2021 19:57:38
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	24 Feb 2021 18:59:11

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:15:35**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	(b) (4), (b) (6)	24 Feb 2021 18:59:11

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'I'	(b) (4), (b) (6)	24 Feb 2021 18:59:11

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	(b) (4), (b) (6)	24 Feb 2021 18:59:11

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)'	(b) (4)	15 Mar 2021 17:45:12
reason for change: Data Entry Error	(b) (4), (b) (6)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	24 Feb 2021 18:59:11

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User closed query ' PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 13:24:14
Query ' PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 17:51:50
User entered 'Acute renal failure improved, now with new baseline renal function' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 17:45:12
User opened query ' PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 14:16:31
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 18:59:11

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the laboratory results for blood culture for bacteria/yeast performed on 13 Feb 2021 and urine culture test performed on 14 Feb 2021.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 15:26:49
Query 'PV Query: Please provide the laboratory results for blood culture for bacteria/yeast performed on 13 Feb 2021 and urine culture test performed on 14 Feb 2021.' answered with 'urine culture was not sent due to negative urinalysis (per notes). Blood culture report not available but infectious workup was otherwise negative per provider notes.' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 16:19:26
User opened query 'PV Query: Please provide the laboratory results for blood culture for bacteria/yeast performed on 13 Feb 2021 and urine culture test performed on 14 Feb 2021.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 22:01:32
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User closed query 'PV Query: Please provide hospital discharge summary, any relevant laboratory and diagnostic test results. 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).	(b) (4), (b) (6)	16 Mar 2021 13:24:24
User closed query 'PV Query: Please provide any additional treatment given for the events 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)	16 Mar 2021 13:24:20
User closed query 'Please confirm if dialysis was performed' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 13:24:17

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Folder: Adverse Events

Form: Adverse Events (5)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide hospital discharge summary, any relevant laboratory and diagnostic test results. 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 'will forward' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 17:53:56
Query 'PV Query: Please provide any additional treatment given for the events 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 'conmeds updated' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 17:52:07
Query 'Please confirm if dialysis was performed' answered with 'no dialysis was done' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 17:51:58
User entered 'AKI ON CKD, SUSPECTED DUE TO CARDIORENAL SYNDROME FROM MI. No dialysis performed, was discharged on oral diuretics' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 17:45:12
User opened query 'PV Query: Please provide hospital discharge summary, any relevant laboratory and diagnostic test results. 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).	(b) (4), (b) (6)	04 Mar 2021 14:17:30
User opened query 'PV Query: Please provide any additional treatment given for the events 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)	04 Mar 2021 14:17:11
User opened query 'Please confirm if dialysis was performed' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 14:16:42

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the hospital discharge date when available.' canceled (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 14:15:03
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 14:14:53
User entered 'AKI on CKD, suspected due to cardiorenal syndrome from MI. Being evaluated for dialysis per records' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 19:12:46
User entered 'sequelae of MI'	(b) (4), (b) (6)	24 Feb 2021 18:59:11

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:15:35**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Feb 2021 18:59:11

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:15:35**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Feb 2021 18:59:11

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:15:35**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Feb 2021 18:59:11

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:15:35**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
Reviewed for Safety.	(b) (4)	25 Feb 2021 19:18:53
User entered 'USA-US120-2021-mRNA-1273-P301000004'	(b) (4), (b) (6)	25 Feb 2021 19:18:47

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:15:35

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:56:41
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure, LLT: Cardiac failure aggravated - version MedDRA\\23.0.	Coder Import (b) (4)	30 Mar 2021 16:37:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Mar 2021 16:37:15
Data point term sent to Coder	System	30 Mar 2021 16:36:15
Signature has been broken.	Christina Bacher (b) (4)	30 Mar 2021 16:35:19
User entered 'WORSENING HEART fAILURE' reason for change: Per Query Resolution	Christina Bacher (b) (4)	30 Mar 2021 16:35:19
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User closed query 'Per DM CLR: Please confirm the AE term "WORSENING HEART FAILURE", as there is no associated baseline Med History condition. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "worsening" from this event. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 15:46:53
Data point term sent to Coder	System	19 Mar 2021 17:23:34
Query 'Per DM CLR: Please confirm the AE term "WORSENING HEART FAILURE", as there is no associated baseline Med History condition. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "worsening" from this event. ' answered with 'Event term updated.	Sarah Wiatrek (b) (4)	19 Mar 2021 17:22:45
Participant has med history of: coronary heart disease, heart attack, atrial fibrillation, pacemaker placement, etc. ' (Site from DM).	(b) (4)	
Coding entries removed.	Sarah Wiatrek (b) (4)	19 Mar 2021 17:22:35

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:15:35

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'WORSENING HEART Condition'	Sarah Wiatrek (b) (4)	19 Mar 2021 17:22:35
reason for change: Per Query Resolution	(b) (4)	
User opened query 'Per DM CLR: Please confirm the	(b) (4), (b) (6)	19 Mar 2021 01:27:32
AE term "WORSENING HEART FAILURE", as		
there is no associated baseline Med History		
condition. Clarify if this condition is an exacerbation		
of a baseline condition. If so, please add the		
corresponding condition to the Med History eCRF.		
Otherwise, consider deleting the term "worsening"		
from this event. ' (Site from DM).		
User coded data point as SOC: Cardiac disorders,	Coder Import (b) (4)	06 Mar 2021 15:29:07
HLGT: Heart failures, HLT: Heart failures NEC, PT:	(b) (4)	
Cardiac failure, LLT: Cardiac failure aggravated -		
version MedDRA\\23.0.		
User coded data point as Term Coded data point by	Coder Import (b) (4)	06 Mar 2021 15:29:07
User: (b) (6) - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	24 Feb 2021 19:01:41
User entered 'Worsening Heart Failure'	(b) (4), (b) (6)	24 Feb 2021 19:00:40

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:15:35**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 19:00:40



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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:15:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Feb 2021 19:01:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Feb 2021 19:01:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 19:01:13
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 19:00:40
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 19:00:40

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:15:35**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'No (N)'	(b) (4), (b) (6)	24 Feb 2021 19:00:40

US3632075

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:15:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '12 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 19:00:40

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:15:35**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 19:00:40

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:15:35**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 19:00:40

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:15:35**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 17:58:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 19:00:40

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:15:35

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4)	
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 'added' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 13:24:34
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 'added' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 17:59:04
User entered '03 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 17:58:51
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 14:19:53
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 19:00:40

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:15:35**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 19:00:40



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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:15:35**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 19:00:40

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:15:35**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	24 Feb 2021 19:00:40

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Folder: Adverse Events

Form: Adverse Events (6)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 19:00:40

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:15:35**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	(b) (4), (b) (6)	24 Feb 2021 19:00:40

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:15:35**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'I'	(b) (4), (b) (6)	24 Feb 2021 19:00:40

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Folder: Adverse Events

Form: Adverse Events (6)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	26 Feb 2021 09:48:46
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'not yet discharged from hospital' (Site from System).	(b) (4), (b) (6)	24 Feb 2021 19:01:22
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	24 Feb 2021 19:00:40
User entered 'I'	(b) (4), (b) (6)	24 Feb 2021 19:00:40

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:15:35

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '12 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 19:00:40

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:15:35

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User closed query 'Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4)	
Query 'Please provide the hospital discharge date when available.' answered with 'added' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 13:24:41
	(b) (4), (b) (6)	15 Mar 2021 18:01:39
User entered '03 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 17:58:51
User opened query 'Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 14:19:28
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 19:00:40



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**Folder: Adverse Events**

**Form: Adverse Events (6)**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'No (N)'	(b) (4), (b) (6)	24 Feb 2021 19:00:40

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Folder: Adverse Events

Form: Adverse Events (6)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 19:00:40

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	(b) (4), (b) (6)	24 Feb 2021 19:00:40

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:15:35**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	(b) (4), (b) (6)	24 Feb 2021 19:00:40

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	(b) (4), (b) (6)	24 Feb 2021 19:00:40

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:15:35**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	24 Feb 2021 19:00:40

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	24 Feb 2021 19:00:40

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Folder: Adverse Events

Form: Adverse Events (6)

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	28 Apr 2021 22:19:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:50:29
DataPoint Un-verified.	Christina Bacher (b) (4)	20 Apr 2021 19:57:55
	(b) (4)	
Signature has been broken.	Christina Bacher (b) (4)	20 Apr 2021 19:57:55
	(b) (4)	
User entered 'None (NONE)' reason for change:	Christina Bacher (b) (4)	20 Apr 2021 19:57:55
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	24 Feb 2021 19:00:40



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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:15:35**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	(b) (4), (b) (6)	24 Feb 2021 19:00:40

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Folder: Adverse Events

Form: Adverse Events (6)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'I'	(b) (4), (b) (6)	24 Feb 2021 19:00:40

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:15:35**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'I'	(b) (4), (b) (6)	24 Feb 2021 19:00:40

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Folder: Adverse Events

Form: Adverse Events (6)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 13:24:45
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 18:01:53
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 17:58:51
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 14:20:27
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	24 Feb 2021 19:00:40

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:52:17
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	(b) (4) System	15 Mar 2021 18:02:58
User entered 'New baseline EF of 15% (was previously higher per records)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 18:02:58
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	15 Mar 2021 17:58:51
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 19:00:40

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Folder: Adverse Events

Form: Adverse Events (6)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:52:45
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 20:19:34
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User closed query 'PV Query: Please provide hospital discharge summary, any relevant laboratory and diagnostic test results. 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).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 13:24:51
User closed query 'PV Query: Please provide any additional treatment given for the events 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)	16 Mar 2021 13:24:48
Query 'PV Query: Please provide hospital discharge summary, any relevant laboratory and diagnostic test results. 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 'will forward' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 18:02:24
Query 'PV Query: Please provide any additional treatment given for the events 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 'added' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 18:02:20

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:15:35

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SEQUELAE OF HOSPITALIZATION DUE TO MI. Echo with new baseline EF of 15%.'	(b) (4), (b) (6)	15 Mar 2021 17:58:51
reason for change: Data Entry Error		
User opened query 'PV Query: Please provide hospital discharge summary, any relevant laboratory and diagnostic test results. 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).	(b) (4), (b) (6)	04 Mar 2021 14:21:04
User opened query 'PV Query: Please provide any additional treatment given for the events 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)	04 Mar 2021 14:20:47
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	24 Feb 2021 19:01:13
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	24 Feb 2021 19:01:13
User entered 'sequelae of hospitalization due to MI'	(b) (4), (b) (6)	24 Feb 2021 19:01:13
reason for change: Data Entry Error		
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	24 Feb 2021 19:00:40
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 19:00:40

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:15:35**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Feb 2021 19:00:40



**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:15:35**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Feb 2021 19:00:40

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:15:35**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Feb 2021 19:00:40

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:15:35**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:33

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:15:35

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:33
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Cystitis, LLT: Cystitis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	04 Mar 2021 16:55:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Mar 2021 16:55:01
Data point term sent to Coder	System	04 Mar 2021 16:53:42
User entered 'Cystitis'	(b) (4), (b) (6)	04 Mar 2021 16:53:15

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:15:35**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:53:07
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 20:19:59
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Mar 2021 16:53:15

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:15:35**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:33
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 16:53:15

US3632075

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:15:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:33
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 16:53:15

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:33
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:53:15



**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:15:35**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:33
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 16:53:15

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:15:35**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:33
User entered empty.	System	04 Mar 2021 16:53:15

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:15:35**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:33
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 16:53:15

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:15:35**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:33
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:53:15

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:15:35**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:33
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 16:53:15

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:15:35**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:33
User entered empty.	System	04 Mar 2021 16:53:15

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:15:35**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:33
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 16:55:01
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	04 Mar 2021 16:53:15

US3632075

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:15:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:33
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 16:53:15



**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:15:35**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:33
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	(b) (4), (b) (6)	04 Mar 2021 16:53:15

US3632075

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:15:35

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:33
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	(b) (4), (b) (6)	04 Mar 2021 16:53:15

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:15:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:33
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	(b) (4), (b) (6)	04 Mar 2021 16:53:15

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:15:35**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:33
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 16:53:15

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:15:35**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:33
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 16:53:15

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:15:35**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:33
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 16:53:15

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:15:35**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:33
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 16:53:15

US3632075

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:15:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:33
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	(b) (4), (b) (6)	04 Mar 2021 16:53:15



**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:15:35**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:33
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	(b) (4), (b) (6)	04 Mar 2021 16:53:15

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:15:35**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:33
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	(b) (4), (b) (6)	04 Mar 2021 16:53:15

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:15:35**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:33
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	04 Mar 2021 16:53:15

US3632075

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:15:35

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:33
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	04 Mar 2021 16:53:15

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:15:35**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:33
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	04 Mar 2021 16:53:15

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:15:35**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:33
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	(b) (4), (b) (6)	04 Mar 2021 16:53:15

US3632075

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:15:35

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:33
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'l'	(b) (4), (b) (6)	04 Mar 2021 16:53:15

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:15:35**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:33
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered '0'	(b) (4), (b) (6)	04 Mar 2021 16:53:15



**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:15:35**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:33
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:53:15

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:15:35**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:33
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 16:53:15

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:15:35**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:33
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:06:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:37
User entered 'occurred during hospitalization. urine culture was not sent due to negative urinalysis but was treated empirically with antibiotics'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:53:15

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:15:35**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:33
User entered '0'	System	04 Mar 2021 16:53:15

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:15:35**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:33
User entered 'I'	System	04 Mar 2021 16:53:15

**US3632075**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:15:35**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:33

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:15:35

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:04:21
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:23:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 18:34:12

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:15:35

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: AMINO ACIDS AND DERIVATIVES, PRODUCT: ACETYLCYSTEINE, PRODUCTSYNONYM: N ACETYL CYSTEINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Oct 2020 05:23:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Oct 2020 05:23:39
Data point term sent to Coder	System	02 Oct 2020 14:00:04
User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	02 Oct 2020 13:59:16
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'Changed from Acronym to Full name. Below is the active ingredient. Oxidative stress, which can increase as a result of deficient glutathione, is known to reduce both cellular insulin sensitivity and beta-cell function' (Site from System).	Bezuayehu Mandefro (b) (4)	02 Oct 2020 13:59:16
Data point term sent to Coder	System	02 Oct 2020 13:58:00
User entered 'N-Acetyl-Cysteine' reason for change: New Information	Bezuayehu Mandefro (b) (4)	02 Oct 2020 13:57:42



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:15:35

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	25 Sep 2020 14:05:42
Data point term sent to Coder	System	14 Sep 2020 20:06:48
User entered 'NAC'	Kelly Likos (b) (4)	14 Sep 2020 20:06:22
	(b) (4)	

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	Kelly Likos (b) (4)	14 Sep 2020 20:06:22

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:15:35

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Type 2 Diabetes'	Kelly Likos (b) (4)	14 Sep 2020 20:06:22

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '600'	Kelly Likos (b) (4)	14 Sep 2020 20:06:22

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:15:35

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'mg (mg)'	Kelly Likos (b) (4)	14 Sep 2020 20:06:22

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:15:35

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:06:22

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:15:35

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'twice daily (BID)'	Kelly Likos (b) (4)	14 Sep 2020 20:06:22

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:15:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:06:22



**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Oral (ORAL)'	Kelly Likos (b) (4)	14 Sep 2020 20:06:22

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:15:35

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:06:22

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '1 UNK 2001' reason for change: Data Entry Error	(b) (4)	14 Sep 2020 20:13:14
User entered '1 Jan 2001'	Kelly Likos (b) (4)	14 Sep 2020 20:06:22
	(b) (4)	

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '0'	Kelly Likos (b) (4)	14 Sep 2020 20:06:22

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Yes (Y)'	Kelly Likos (b) (4)	14 Sep 2020 20:06:22

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:15:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:06:22

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:15:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	Kelly Likos (b) (4)	14 Sep 2020 20:06:22

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	14 Sep 2020 20:06:22



**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 20:06:22

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 20:06:22

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:15:35

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: VITIS VINIFERA SEED, PRODUCTSYNONYM: GRAPE SEED EXTRACT [VITIS VINIFERA SEED] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 13:55:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 13:55:35
Data point term sent to Coder	System	14 Sep 2020 20:07:50
User entered 'Grape Seed Extract'	Kelly Likos (b) (4)	14 Sep 2020 20:07:41

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:15:35

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	Kelly Likos (b) (4)	14 Sep 2020 20:07:41

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:15:35

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Type 2 Diabetes'	Kelly Likos (b) (4)	14 Sep 2020 20:07:41

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '400'	Kelly Likos (b) (4)	14 Sep 2020 20:07:41

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:15:35

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'mg (mg)'	Kelly Likos (b) (4)	14 Sep 2020 20:07:41

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:15:35

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:07:41



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:15:35

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'twice daily (BID)'	Kelly Likos (b) (4)	14 Sep 2020 20:07:41

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:15:35

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:07:41

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Oral (ORAL)'	Kelly Likos (b) (4)	14 Sep 2020 20:07:41

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:15:35

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:07:41

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '1 UNK 2005' reason for change: Data Entry Error	Kelly Likos (b) (4)	14 Sep 2020 20:13:04
User entered '1 Jan 2005'	Kelly Likos (b) (4)	14 Sep 2020 20:07:41

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:15:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '0'	Kelly Likos (b) (4)	14 Sep 2020 20:07:41

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Yes (Y)'	Kelly Likos (b) (4)	14 Sep 2020 20:07:41

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:15:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:07:41



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:15:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	Kelly Likos (b) (4)	14 Sep 2020 20:07:41

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	14 Sep 2020 20:07:41

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 20:07:41

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 20:07:41

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:15:35

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 20:31:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 20:31:06
Data point term sent to Coder Coding entries removed.	System Christina Bacher (b) (4) (b) (4)	22 Apr 2021 20:30:32 22 Apr 2021 20:30:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	12 Apr 2021 01:34:58
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) (b) (4)	09 Oct 2020 00:05:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 00:05:21
Data point term sent to Coder Coding entries removed.	System Isaac Perez (b) (4) (b) (4)	08 Oct 2020 20:24:32 08 Oct 2020 20:23:51

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:15:35

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 20:10:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 20:10:48
Data point term sent to Coder	System	14 Sep 2020 20:09:52
User entered 'Aspirin'	Kelly Likos (b) (4) (b) (4)	14 Sep 2020 20:08:57

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:15:35

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Yes (Y)'	Kelly Likos (b) (4)	14 Sep 2020 20:08:57

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:15:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	28 Apr 2021 22:19:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 21:29:43
Signature has been broken.	Christina Bacher (b) (4)	22 Apr 2021 20:30:31
	(b) (4)	
User entered 'MI PREVENTION' reason for change:	Christina Bacher (b) (4)	22 Apr 2021 20:30:31
Data Entry Error	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:47:07
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
	(b) (4), (b) (6)	
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
	(b) (4)	
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.	(b) (4), (b) (6)	12 Oct 2020 12:43:59
' (Site from DM).		
Query 'Per DM CLR: Please update the indication of Isaac Perez this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.	(b) (4)	08 Oct 2020 20:23:58
' answered with 'Updated indication.' (Site from DM).	(b) (4)	
User entered 'Heart Attack Prevention' reason for change: Data Entry Error	Isaac Perez (b) (4)	08 Oct 2020 20:23:51
	(b) (4)	
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.	(b) (4), (b) (6)	05 Oct 2020 20:09:32
	(b) (4), (b) (6)	
' (Site from DM).		
User entered 'Prevention'	Kelly Likos (b) (4)	14 Sep 2020 20:08:57
	(b) (4)	



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:15:35

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '81'	Kelly Likos (b) (4)	14 Sep 2020 20:08:57

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:15:35

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'mg (mg)'	Kelly Likos (b) (4)	14 Sep 2020 20:08:57

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:15:35

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:08:57

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:15:35

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'once daily (QD)'	Kelly Likos (b) (4)	14 Sep 2020 20:08:57

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:15:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:08:57

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:15:35

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Oral (ORAL)'	Kelly Likos (b) (4)	14 Sep 2020 20:08:57

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:15:35

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:08:57

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '1 UNK 2015' reason for change: Data Entry Error	Kelly Likos (b) (4)	14 Sep 2020 20:12:56
User entered '1 Jan 2015'	Kelly Likos (b) (4)	14 Sep 2020 20:08:57



US3632075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '0'	Kelly Likos (b) (4)	14 Sep 2020 20:08:57

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:15:35

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Yes (Y)'	Kelly Likos (b) (4)	14 Sep 2020 20:08:57

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:15:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:08:57

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:15:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	Kelly Likos (b) (4)	14 Sep 2020 20:08:57

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:15:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 20:08:57

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 20:08:57

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 20:08:57

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:35

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: VITAMIN K ANTAGONISTS, PRODUCT: WARFARIN SODIUM, PRODUCTSYNONYM: COUMADIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Sep 2020 17:04:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Sep 2020 17:04:40
Data point term sent to Coder	System	21 Sep 2020 17:03:27
User closed query 'DM-Coding: Please check the spelling of the medication. If the spelling is correct, enter the active ingredients in parentheses (...) following the drug name.' (Site from System).	System	21 Sep 2020 17:03:10
Query 'DM-Coding: Please check the spelling of the medication. If the spelling is correct, enter the active ingredients in parentheses (...) following the drug name.' answered with 'Spelling corrected.' (Site from System).	Isaac Perez (b) (4)	21 Sep 2020 17:03:10
User entered 'COUMADIN' reason for change: Data Entry Error	Isaac Perez (b) (4)	21 Sep 2020 17:03:03
Data point term sent to Coder	System	18 Sep 2020 14:06:50
User entered 'CAMADIN' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 14:06:45
User entered 'COUMADIN' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 14:06:28
User opened query 'DM-Coding: Please check the spelling of the medication. If the spelling is correct, enter the active ingredients in parentheses (...) following the drug name.' (Site from System).	Coder Import (b) (4)	15 Sep 2020 12:26:36
Data point term sent to Coder	System	14 Sep 2020 20:11:55
User entered 'CAMADIN'	Kelly Likos (b) (4)	14 Sep 2020 20:11:00



**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:15:35**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	Kelly Likos (b) (4)	14 Sep 2020 20:11:00

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:35

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'ATRIAL FIBRILLATION'	Kelly Likos (b) (4)	14 Sep 2020 20:11:00

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:35

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '2.5' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 18:08:39
User entered '22-27'	Kelly Likos (b) (4)	14 Sep 2020 20:11:00

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:35

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'mg (mg)'	Kelly Likos (b) (4)	14 Sep 2020 20:11:00

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:35

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:11:00

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:35

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'other (OTHER)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:08:39
User entered 'every week (QS)'	Kelly Likos (b) (4) (b) (4)	14 Sep 2020 20:11:00

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:35

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User closed query 'Per DM CLR: Please ensure that tapering doses are reflected in separate entries. Update as appropriate. ' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please ensure that tapering doses are reflected in separate entries. Update as appropriate. ' answered with 'Updated into separate entries' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 10:29:28
Query 'Per DM CLR: Please ensure that tapering doses are reflected in separate entries. Update as appropriate. ' answered with 'Updated into separate entries' (Site from DM).	Isaac Perez (b) (4)	05 Apr 2021 18:21:46
User entered '2.5 MG MONDAY, TUESDAY, THURSDAY, AND FRIDAY' reason for change:	(b) (4)	
Data Entry Error	Isaac Perez (b) (4)	05 Apr 2021 18:21:19
User opened query 'Per DM CLR: Please ensure that tapering doses are reflected in separate entries. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 03:39:49
User entered '5mg on Wednesday, saturday, sunday and 2.5 mg monday, tuesday, thursday, and Friday' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 18:08:39
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:11:00
	(b) (4)	

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:15:35**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Oral (ORAL)'	Kelly Likos (b) (4)	14 Sep 2020 20:11:00



US3632075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:15:35**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:11:00

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '03 Mar 2021' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	15 Mar 2021 18:08:39
User entered '1 UNK 2015' reason for change: Data Entry Error	Kelly Likos (b) (4)	14 Sep 2020 20:12:46
	(b) (4)	
User entered '1 Jan 2015'	Kelly Likos (b) (4)	14 Sep 2020 20:11:00
	(b) (4)	

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '0'	Kelly Likos (b) (4)	14 Sep 2020 20:11:00

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:35

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Yes (Y)'	Kelly Likos (b) (4)	14 Sep 2020 20:11:00

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:11:00

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	Kelly Likos (b) (4)	14 Sep 2020 20:11:00

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:15:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Mar 2021 18:08:39
User entered '1'	System	14 Sep 2020 20:11:00

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Mar 2021 18:08:39
User entered '1'	System	14 Sep 2020 20:11:00



**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Mar 2021 18:08:39
User entered '803 (803)'	System	14 Sep 2020 20:11:00

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	(b) (4) Coders Import (b) (4) (b) (4)	14 Sep 2020 20:13:50
User coded data point as Term Coded data point by User: Coders System - version WHODrug-Global-B3\\202003.	Coders Import (b) (4) (b) (4)	14 Sep 2020 20:13:50
Data point term sent to Coders	System	14 Sep 2020 20:12:56
User entered 'CARVEDILOL'	Kelly Likos (b) (4) (b) (4)	14 Sep 2020 20:12:37

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4) Kelly Likos (b) (4) (b) (4)	14 Sep 2020 20:12:37

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'CORONARY ARTERY DISEASE'	(b) (4) Kelly Likos (b) (4) (b) (4)	14 Sep 2020 20:12:37

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '6.25' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 19:33:47
User entered '22-27'	Kelly Likos (b) (4)	14 Sep 2020 20:12:37

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'mg (mg)'	(b) (4) Kelly Likos (b) (4) (b) (4)	14 Sep 2020 20:12:37

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:15:35**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4) Kelly Likos (b) (4) (b) (4)	14 Sep 2020 20:12:37

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:29
User signature succeeded.	Colleen Kelley (b) (4)	28 Apr 2021 22:19:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 21:30:07
User closed query 'This is noted as twice a day in the source; please verify and update EDC.' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 21:30:04
Query 'This is noted as twice a day in the source; please verify and update EDC.' answered with 'updated' (Site from CRA).	Christina Bacher (b) (4)	22 Apr 2021 20:22:45
Signature has been broken.	(b) (4)	
	Christina Bacher (b) (4)	22 Apr 2021 20:22:22
User entered 'twice daily (BID)' reason for change:	(b) (4)	
Data Entry Error	Christina Bacher (b) (4)	22 Apr 2021 20:22:22
	(b) (4)	
User opened query 'This is noted as twice a day in the source; please verify and update EDC.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 19:50:58
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:49:09
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'every week (QS)'	(b) (4)	
	Kelly Likos (b) (4)	14 Sep 2020 20:12:37
	(b) (4)	



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:29
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 21:30:09
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:51:00
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4) Kelly Likos (b) (4) (b) (4)	14 Sep 2020 20:12:37

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:15:35**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Oral (ORAL)'	(b) (4) Kelly Likos (b) (4) (b) (4)	14 Sep 2020 20:12:37

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4) Kelly Likos (b) (4) (b) (4)	14 Sep 2020 20:12:37

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '1 UNK 2015'	(b) (4) Kelly Likos (b) (4) (b) (4)	14 Sep 2020 20:12:37

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '0'	(b) (4) Kelly Likos (b) (4) (b) (4)	14 Sep 2020 20:12:37

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:14:11
User entered 'Yes (Y)'	Kelly Likos (b) (4)	14 Sep 2020 20:12:37

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '12 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:14:11
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:12:37

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4) Kelly Likos (b) (4) (b) (4)	14 Sep 2020 20:12:37



US3632075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:15:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:29
User entered '2'	System	22 Apr 2021 20:22:22
User entered '1'	System	14 Sep 2020 20:12:37

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:29
User entered '1'	System	14 Sep 2020 20:12:37

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:29
User entered '804 (804)'	System	22 Apr 2021 20:22:22
User entered '803 (803)'	System	14 Sep 2020 20:12:37

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:15:35

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: OTHER DIURETICS, PRODUCT: ISOSORBIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 20:16:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 20:16:48
Data point term sent to Coder User entered 'ISOSORBIDE'	System Kelly Likos (b) (4)	14 Sep 2020 20:16:00 14 Sep 2020 20:15:23

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:15:35

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	Kelly Likos (b) (4)	14 Sep 2020 20:15:23

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:15:35

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'CORONARY ARTERY DISEASE'	Kelly Likos (b) (4)	14 Sep 2020 20:15:23

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:15:35

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '60'	Kelly Likos (b) (4)	14 Sep 2020 20:15:23

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:15:35

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'mg (mg)'	Kelly Likos (b) (4)	14 Sep 2020 20:15:23



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:15:35

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:15:23

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:15:35**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'as needed (PRN)' reason for change: New Information	(b) (4), (b) (6)	30 Mar 2021 18:21:02
User entered 'once daily (QD)'	Kelly Likos (b) (4)	14 Sep 2020 20:15:23

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:15:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:15:23

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:15:35

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Oral (ORAL)'	Kelly Likos (b) (4)	14 Sep 2020 20:15:23

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:15:35

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:15:23

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:15:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of CORONARY ARTERY DISEASE. Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Oct 2020 06:48:20
Query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of CORONARY ARTERY DISEASE. Please review and reconcile Con Med and Med History start dates as appropriate. ' answered with 'updated' (Site from DM).	Christina Bacher (b) (4) (b) (4)	13 Oct 2020 20:08:49
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of CORONARY ARTERY DISEASE. Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 20:10:02
User entered '1 UNK 2005'	Kelly Likos (b) (4) (b) (4)	14 Sep 2020 20:15:23

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '0'	Kelly Likos (b) (4)	14 Sep 2020 20:15:23

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:15:35**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Yes (Y)'	Kelly Likos (b) (4)	14 Sep 2020 20:15:23



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:15:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:15:23

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:15:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	Kelly Likos (b) (4)	14 Sep 2020 20:15:23

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:15:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 18:21:02
User entered '1'	System	14 Sep 2020 20:15:23

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 18:21:02
User entered '1'	System	14 Sep 2020 20:15:23

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 18:21:02
User entered '804 (804)'	System	14 Sep 2020 20:15:23

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:15:35

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS, PRODUCT: SITAGLIPTIN, PRODUCTSYNONYM: JANUVIA [SITAGLIPTIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Sep 2020 07:15:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Sep 2020 07:15:35
Data point term sent to Coder	System	14 Sep 2020 20:17:02
User entered 'GENUUIA'	Kelly Likos (b) (4)	14 Sep 2020 20:16:51

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:15:35

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	Kelly Likos (b) (4)	14 Sep 2020 20:16:51

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:15:35**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'TYPE 2 DIABETES'	Kelly Likos (b) (4)	14 Sep 2020 20:16:51



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:15:35

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '25'	Kelly Likos (b) (4)	14 Sep 2020 20:16:51

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:15:35

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'mg (mg)'	Kelly Likos (b) (4)	14 Sep 2020 20:16:51

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:15:35

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:16:51

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:15:35

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'once daily (QD)'	Kelly Likos (b) (4)	14 Sep 2020 20:16:51

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:15:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:16:51

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:15:35**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Oral (ORAL)'	Kelly Likos (b) (4)	14 Sep 2020 20:16:51

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:15:35

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:16:51

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:15:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '1 UNK 2010'	Kelly Likos (b) (4)	14 Sep 2020 20:16:51



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:15:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '0'	Kelly Likos (b) (4)	14 Sep 2020 20:16:51

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:15:35**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Yes (Y)'	Kelly Likos (b) (4)	14 Sep 2020 20:16:51

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:15:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:16:51

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:15:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	Kelly Likos (b) (4)	14 Sep 2020 20:16:51

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:15:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 20:16:51

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 20:16:51

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 20:16:51

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:15:35

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 00:05:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 00:05:22
Data point term sent to Coder Coding entries removed.	System Isaac Perez (b) (4)	08 Oct 2020 20:25:35 08 Oct 2020 20:24:43
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 23:42:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 23:42:53
Data point term sent to Coder User entered 'VITAMIN D'	System Kelly Likos (b) (4)	14 Sep 2020 20:19:04 14 Sep 2020 20:18:20



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:15:35

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:09:49
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'Data entry error' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 14:50:56
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Nov 2020 14:50:45
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 15:16:09
User entered 'No (N)'	Kelly Likos (b) (4) (b) (4)	14 Sep 2020 20:18:20

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:15:35

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
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. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:11:12
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'Updated Indication' (Site from DM).	Isaac Perez (b) (4) (b) (4)	08 Oct 2020 20:24:52
User entered 'GENERAL SUPPLEMENT' reason for change: Data Entry Error	Isaac Perez (b) (4) (b) (4)	08 Oct 2020 20:24:43
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. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 20:10:27
User entered 'GENERAL'	Kelly Likos (b) (4) (b) (4)	14 Sep 2020 20:18:20

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:15:35

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '5000'	Kelly Likos (b) (4)	14 Sep 2020 20:18:20

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:15:35

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Other (OTHER)'	Kelly Likos (b) (4)	14 Sep 2020 20:18:20

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:15:35

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'UNITS'	Kelly Likos (b) (4)	14 Sep 2020 20:18:20

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:15:35

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'once daily (QD)'	Kelly Likos (b) (4)	14 Sep 2020 20:18:20

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:15:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:18:20

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:15:35**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Oral (ORAL)'	Kelly Likos (b) (4)	14 Sep 2020 20:18:20



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:15:35

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:18:20

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:15:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '1 UNK 2018'	Kelly Likos (b) (4)	14 Sep 2020 20:18:20

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:15:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '0'	Kelly Likos (b) (4)	14 Sep 2020 20:18:20

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:15:35**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Yes (Y)'	Kelly Likos (b) (4)	14 Sep 2020 20:18:20

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:15:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:18:20

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:15:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	Kelly Likos (b) (4)	14 Sep 2020 20:18:20

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:15:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 20:18:20

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 20:18:20



**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 20:18:20

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:15:35

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: OTHER CARDIAC PREPARATIONS, ATC: OTHER CARDIAC PREPARATIONS, PRODUCT: UBIQUINOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 05:19:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 05:19:44
Data point term sent to Coder	System	14 Sep 2020 20:20:07
User entered 'UBIQUINOL'	Kelly Likos (b) (4)	14 Sep 2020 20:19:33

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:15:35

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	Kelly Likos (b) (4)	14 Sep 2020 20:19:33

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:15:35

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'CORONARY ARTERY DISEASE'	Kelly Likos (b) (4)	14 Sep 2020 20:19:33

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:15:35

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '100'	Kelly Likos (b) (4)	14 Sep 2020 20:19:33

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:15:35

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'mg (mg)'	Kelly Likos (b) (4)	14 Sep 2020 20:19:33

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:15:35

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:19:33

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:15:35

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'four times daily (QID)'	Kelly Likos (b) (4)	14 Sep 2020 20:19:33



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:15:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:19:33

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:15:35

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Oral (ORAL)'	Kelly Likos (b) (4)	14 Sep 2020 20:19:33

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:15:35

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:19:33

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:15:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '1 UNK 2018'	Kelly Likos (b) (4)	14 Sep 2020 20:19:33

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:15:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '0'	Kelly Likos (b) (4)	14 Sep 2020 20:19:33

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:15:35**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Yes (Y)'	Kelly Likos (b) (4)	14 Sep 2020 20:19:33

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:15:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:19:33

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:15:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	Kelly Likos (b) (4)	14 Sep 2020 20:19:33



**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:15:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	14 Sep 2020 20:19:33

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 20:19:33

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 20:19:33

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:15:35

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: CARBOHYDRATES, PRODUCT: D-RIBOSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 13:19:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 13:19:54
Data point term sent to Coder	System	14 Sep 2020 20:22:09
User entered 'D-RIBOSE'	Kelly Likos (b) (4)	14 Sep 2020 20:21:31

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:15:35

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	Kelly Likos (b) (4)	14 Sep 2020 20:21:31

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:15:35

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'CORONARY ARTERY DISEASE'	Kelly Likos (b) (4)	14 Sep 2020 20:21:31

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:15:35

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '5'	Kelly Likos (b) (4)	14 Sep 2020 20:21:31

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:15:35

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'g (g)'	Kelly Likos (b) (4)	14 Sep 2020 20:21:31



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:15:35

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:21:31

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:15:35

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'once daily (QD)'	Kelly Likos (b) (4)	14 Sep 2020 20:21:31

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:15:35

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:21:31

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:15:35

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Oral (ORAL)'	Kelly Likos (b) (4)	14 Sep 2020 20:21:31

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:15:35

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:21:31

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:15:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '1 UNK 2017'	Kelly Likos (b) (4)	14 Sep 2020 20:21:31

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '0'	Kelly Likos (b) (4)	14 Sep 2020 20:21:31

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:15:35

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Yes (Y)'	Kelly Likos (b) (4)	14 Sep 2020 20:21:31



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:15:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:21:31

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:15:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	Kelly Likos (b) (4)	14 Sep 2020 20:21:31

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:15:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 20:21:31

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 20:21:31

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 20:21:31

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:15:35

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: OTHER CARDIAC PREPARATIONS, ATC: OTHER CARDIAC PREPARATIONS, PRODUCT: CARNITINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 00:54:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 00:54:49
Data point term sent to Coder	System	14 Sep 2020 20:24:13
User entered 'CARNITINE'	Kelly Likos (b) (4)	14 Sep 2020 20:23:42

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:15:35

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	Kelly Likos (b) (4)	14 Sep 2020 20:23:42

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:15:35

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'CORONARY ARTERY DISEASE'	Kelly Likos (b) (4)	14 Sep 2020 20:23:42



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:15:35

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '500'	Kelly Likos (b) (4)	14 Sep 2020 20:23:42

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:15:35

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'mg (mg)'	Kelly Likos (b) (4)	14 Sep 2020 20:23:42

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:15:35

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:23:42

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:15:35

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'twice daily (BID)'	Kelly Likos (b) (4)	14 Sep 2020 20:23:42

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:15:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:23:42

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:15:35**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Oral (ORAL)'	Kelly Likos (b) (4)	14 Sep 2020 20:23:42

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:15:35

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:23:42

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:15:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '1 UNK 2017'	Kelly Likos (b) (4)	14 Sep 2020 20:23:42



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:15:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '0'	Kelly Likos (b) (4)	14 Sep 2020 20:23:42

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:15:35**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Yes (Y)'	Kelly Likos (b) (4)	14 Sep 2020 20:23:42

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:15:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:23:42

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:15:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	Kelly Likos (b) (4)	14 Sep 2020 20:23:42

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:15:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	14 Sep 2020 20:23:42

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 20:23:42

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 20:23:42

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:15:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:21
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Sep 2020 06:31:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 06:31:44
Data point term sent to Coder	System	14 Sep 2020 20:26:17
User entered 'LASIX'	Kelly Likos (b) (4) (b) (4)	14 Sep 2020 20:25:23



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:15:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:21
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4) Kelly Likos (b) (4) (b) (4)	14 Sep 2020 20:25:23

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:15:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:21
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:08:18
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 20:02:56
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'LEFT LEG AMPUTATION'	(b) (4) Kelly Likos (b) (4) (b) (4)	14 Sep 2020 20:25:23

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:15:35**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:21
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '20'	(b) (4) Kelly Likos (b) (4) (b) (4)	14 Sep 2020 20:25:23

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:15:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:21
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'mg (mg)'	(b) (4) Kelly Likos (b) (4) (b) (4)	14 Sep 2020 20:25:23

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:15:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:21
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4) Kelly Likos (b) (4) (b) (4)	14 Sep 2020 20:25:23

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:15:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:21
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'other (OTHER)'	(b) (4) Kelly Likos (b) (4) (b) (4)	14 Sep 2020 20:25:23

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:15:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:21
User signature succeeded.	Colleen Kelley (b) (4)	28 Apr 2021 22:19:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 21:31:26
User closed query 'Source notes this as just 2-3 X week; please review and update EDC/source to clarify if "once" should be added to source or removed from EDC.' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 21:31:21
Query 'Source notes this as just 2-3 X week; please review and update EDC/source to clarify if "once" should be added to source or removed from EDC.' answered with 'updated' (Site from CRA).	Christina Bacher (b) (4)	22 Apr 2021 20:24:55
Signature has been broken.	(b) (4)	
	Christina Bacher (b) (4)	22 Apr 2021 20:24:38
User entered '2-3 times a week' reason for change:	(b) (4)	
Data Entry Error	Christina Bacher (b) (4)	22 Apr 2021 20:24:38
User opened query 'Source notes this as just 2-3 X week; please review and update EDC/source to clarify if "once" should be added to source or removed from EDC.' (Site from CRA).	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 20:07:00
	(b) (4), (b) (6)	21 Apr 2021 20:04:27
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'ONCE EVERY 2 OR 3 WEEKS'	(b) (4)	
	Kelly Likos (b) (4)	14 Sep 2020 20:25:23
	(b) (4)	

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:15:35**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:21
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Oral (ORAL)'	(b) (4) Kelly Likos (b) (4) (b) (4)	14 Sep 2020 20:25:23



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:15:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:21
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4) Kelly Likos (b) (4) (b) (4)	14 Sep 2020 20:25:23

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:21
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '1 UNK 2018'	(b) (4) Kelly Likos (b) (4) (b) (4)	14 Sep 2020 20:25:23

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:21
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '0'	(b) (4) Kelly Likos (b) (4) (b) (4)	14 Sep 2020 20:25:23

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:15:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:21
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:28:47
User entered 'Yes (Y)'	Kelly Likos (b) (4)	14 Sep 2020 20:25:23

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:15:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:21
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '01 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:28:47
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:25:23

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:15:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:21
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4) Kelly Likos (b) (4) (b) (4)	14 Sep 2020 20:25:23

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:15:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:21
User entered empty.	System	14 Sep 2020 20:25:23

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:21
User entered empty.	System	14 Sep 2020 20:25:23



**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:21
User entered empty.	System	14 Sep 2020 20:25:23

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:15:35

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 20:27:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 20:27:49
Data point term sent to Coder User entered 'LIPITOR'	System Kelly Likos (b) (4)	14 Sep 2020 20:26:17 14 Sep 2020 20:26:15

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:15:35

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	Kelly Likos (b) (4)	14 Sep 2020 20:26:15

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:15:35**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'CORONARY ARTERY DISEASE'	Kelly Likos (b) (4)	14 Sep 2020 20:26:15

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:15:35

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '80'	Kelly Likos (b) (4)	14 Sep 2020 20:26:15

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:15:35

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'mg (mg)'	Kelly Likos (b) (4)	14 Sep 2020 20:26:15

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:15:35

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:26:15

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:15:35

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'once daily (QD)'	Kelly Likos (b) (4)	14 Sep 2020 20:26:15



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:15:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:26:15

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:15:35**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Oral (ORAL)'	Kelly Likos (b) (4)	14 Sep 2020 20:26:15

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:15:35

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:26:15

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:15:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '1 UNK 2015'	Kelly Likos (b) (4)	14 Sep 2020 20:26:15

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '0'	Kelly Likos (b) (4)	14 Sep 2020 20:26:15

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:15:35**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Yes (Y)'	Kelly Likos (b) (4)	14 Sep 2020 20:26:15

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:15:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:26:15

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:15:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	Kelly Likos (b) (4)	14 Sep 2020 20:26:15



**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:15:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 20:26:15

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 20:26:15

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 20:26:15

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:15:35

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 06:18:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 06:18:38
Data point term sent to Coder	System	14 Sep 2020 20:28:21
User entered 'MONTELUKAST'	Kelly Likos (b) (4)	14 Sep 2020 20:27:39

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:15:35

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	Kelly Likos (b) (4)	14 Sep 2020 20:27:39

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:15:35

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'SEVERE RENAL DISEASE'	Kelly Likos (b) (4)	14 Sep 2020 20:27:39

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:15:35

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '10'	Kelly Likos (b) (4)	14 Sep 2020 20:27:39

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:15:35

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'mg (mg)'	Kelly Likos (b) (4)	14 Sep 2020 20:27:39



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:15:35

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:27:39

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:15:35

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'once daily (QD)'	Kelly Likos (b) (4)	14 Sep 2020 20:27:39

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:15:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:27:39

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:15:35

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Oral (ORAL)'	Kelly Likos (b) (4)	14 Sep 2020 20:27:39

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:15:35

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:27:39

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:15:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '1 UNK 2020'	Kelly Likos (b) (4)	14 Sep 2020 20:27:39

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:15:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '0'	Kelly Likos (b) (4)	14 Sep 2020 20:27:39

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:15:35**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Yes (Y)'	Kelly Likos (b) (4)	14 Sep 2020 20:27:39



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:15:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Kelly Likos (b) (4)	14 Sep 2020 20:27:39

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:15:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	Kelly Likos (b) (4)	14 Sep 2020 20:27:39

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:15:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 20:27:39

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 20:27:39

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 20:27:39

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:15:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:26
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 15:20:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 15:20:36
Data point term sent to Coder	System	19 Oct 2020 13:47:30
User entered 'Metronidazole'	Sarah Wiatrek (b) (4)	19 Oct 2020 13:47:17

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:15:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:26
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:47:17

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:15:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:26
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Diarrhea'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:47:17



**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:15:35**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:26
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '500'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:47:17

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:15:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:26
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'mg (mg)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:47:17

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:15:35**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:26
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:47:17

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:15:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:26
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'once (ONCE)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:47:17

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:15:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:26
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:47:17

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:15:35**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:26
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Oral (ORAL)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:47:17

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:15:35**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:26
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:47:17

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:26
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '15 Oct 2020'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:47:17



**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:26
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '0'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:47:17

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:15:35**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:26
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:47:17

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:15:35**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:26
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '15 Oct 2020'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:47:17

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:15:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:26
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	19 Oct 2020 13:47:17

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:15:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:26
User entered empty.	System	19 Oct 2020 13:47:17

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:26
User entered empty.	System	19 Oct 2020 13:47:17

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:26
User entered empty.	System	19 Oct 2020 13:47:17

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:15:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:35
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 15:59:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 15:59:58
Data point term sent to Coder	System	30 Oct 2020 14:42:43
Coding entries removed.	Aastha KC (b) (4)	30 Oct 2020 14:42:33
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 14:40:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 14:40:59
Data point term sent to Coder	System	30 Oct 2020 14:39:38
User entered 'Flu Shot'	Aastha KC (b) (4)	30 Oct 2020 14:38:55



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:15:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:35
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	(b) (4), (b) (6)	22 Jan 2021 03:28:52
' (Site from DM).		
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	(b) (4), (b) (6)	21 Jan 2021 14:24:39
' answered with 'Updated' (Site from DM).		
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 14:24:29
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	(b) (4), (b) (6)	13 Jan 2021 23:08:42
' (Site from DM).		
User entered 'No (N)'	Aastha KC (b) (4)	30 Oct 2020 14:38:55
	(b) (4)	

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:15:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:35
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Seasonal FLU SHOT' reason for change: Data Entry Error	(b) (4)	
	Aastha KC (b) (4)	30 Oct 2020 14:42:33
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	30 Oct 2020 14:39:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Oct 2020 14:39:13
User entered 'Flu Shot' reason for change: Data Entry Error	Aastha KC (b) (4)	30 Oct 2020 14:39:13
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 14:38:55
User entered empty.	Aastha KC (b) (4)	30 Oct 2020 14:38:55
	(b) (4)	

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:15:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:35
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	30 Oct 2020 14:42:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Oct 2020 14:42:15
User entered 'Unknown' reason for change: Data Entry Error	Aastha KC (b) (4)	30 Oct 2020 14:42:15
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	30 Oct 2020 14:38:55
User entered empty.	System	30 Oct 2020 14:38:55
	Aastha KC (b) (4)	30 Oct 2020 14:38:55
	(b) (4)	

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:15:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:35
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	30 Oct 2020 14:42:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Oct 2020 14:42:15
User entered 'Other (OTHER)' reason for change:	Aastha KC (b) (4)	30 Oct 2020 14:42:15
Data Entry Error	(b) (4)	30 Oct 2020 14:38:55
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 14:38:55
User entered empty.	Aastha KC (b) (4)	30 Oct 2020 14:38:55
	(b) (4)	

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:15:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:35
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	(b) (4) System	30 Oct 2020 14:42:25
User entered 'unknown' reason for change: Data Entry Error	Aastha KC (b) (4) (b) (4)	30 Oct 2020 14:42:25
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	30 Oct 2020 14:42:15
User entered empty.	Aastha KC (b) (4) (b) (4)	30 Oct 2020 14:38:55

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:15:35**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:35
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'once (ONCE)'	(b) (4) Aastha KC (b) (4) (b) (4)	30 Oct 2020 14:38:55

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:15:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:35
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4) Aastha KC (b) (4) (b) (4)	30 Oct 2020 14:38:55

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:15:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:35
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Aastha KC (b) (4) (b) (4)	30 Oct 2020 14:38:55



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:15:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:35
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4) Aastha KC (b) (4) (b) (4)	30 Oct 2020 14:38:55

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:35
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '27 Sep 2020'	(b) (4) Aastha KC (b) (4) (b) (4)	30 Oct 2020 14:38:55

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:35
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '0'	(b) (4) Aastha KC (b) (4) (b) (4)	30 Oct 2020 14:38:55

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:15:35**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:35
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4) Aastha KC (b) (4) (b) (4)	30 Oct 2020 14:38:55

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:15:35**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:35
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '27 Sep 2020'	(b) (4) Aastha KC (b) (4) (b) (4)	30 Oct 2020 14:38:55

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:15:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:35
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4) Aastha KC (b) (4) (b) (4)	30 Oct 2020 14:38:55

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:15:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:35
User entered empty.	System	30 Oct 2020 14:38:55

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:35
User entered empty.	System	30 Oct 2020 14:38:55



**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:35
User entered empty.	System	30 Oct 2020 14:38:55

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:15:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Mar 2021 11:47:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Mar 2021 11:47:50
Data point term sent to Coder	System	15 Feb 2021 15:36:15
User entered 'Metronidazole'	Sarah Wiatrek (b) (4)	15 Feb 2021 15:35:21

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:15:35**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	15 Feb 2021 15:35:21

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:15:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Diarrhea ( AE)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	15 Feb 2021 15:35:21

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:15:35**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '500'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	15 Feb 2021 15:35:21

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:15:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'mg (mg)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	15 Feb 2021 15:35:21

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:15:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	15 Feb 2021 15:35:21

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:15:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'twice daily (BID)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	15 Feb 2021 15:35:21



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:15:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	15 Feb 2021 15:35:21

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:15:35**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Oral (ORAL)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	15 Feb 2021 15:35:21

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:15:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	15 Feb 2021 15:35:21

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:15:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '23 Oct 2020'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	15 Feb 2021 15:35:21

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '0'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	15 Feb 2021 15:35:21

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:15:35**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	15 Feb 2021 15:35:21

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:15:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '23 Oct 2020'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	15 Feb 2021 15:35:21

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:15:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	15 Feb 2021 15:35:21



**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:15:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:39
User entered '2'	System	15 Feb 2021 15:35:21

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:39
User entered '1'	System	15 Feb 2021 15:35:21

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:15:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:39
User entered '804 (804)'	System	15 Feb 2021 15:35:21

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:15:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:42
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 20:41:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 20:41:05
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 20:26:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 20:26:05
Data point term sent to Coder	System	04 Mar 2021 17:04:00
User entered 'CEftriaxone'	(b) (4), (b) (6)	04 Mar 2021 17:03:40

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:15:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:42
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 17:03:40

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:15:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:42
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Cystitis'	(b) (4), (b) (6)	04 Mar 2021 17:03:40

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:15:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:42
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'l'	(b) (4), (b) (6)	04 Mar 2021 17:03:40

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:15:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:42
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'g (g)'	(b) (4), (b) (6)	04 Mar 2021 17:03:40



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:15:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:42
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 17:03:40

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:15:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:42
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'once daily (QD)'	(b) (4), (b) (6)	04 Mar 2021 17:03:40

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:15:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:42
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 17:03:40

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:15:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:42
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	04 Mar 2021 17:03:40

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:15:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:42
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 17:03:40

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:15:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:42
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '13 Feb 2021'	(b) (4), (b) (6)	04 Mar 2021 17:03:40

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:42
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '0'	(b) (4), (b) (6)	04 Mar 2021 17:03:40

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:15:35**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:42
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 17:03:40



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:15:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:42
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:03:40

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:15:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:42
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 17:03:40

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:15:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:42
User entered '1'	System	04 Mar 2021 17:03:40

US3632075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:42
User entered '1'	System	04 Mar 2021 17:03:40

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:42
User entered '804 (804)'	System	04 Mar 2021 17:03:40

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:15:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:44
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: PHOSPHODIESTERASE INHIBITORS, PRODUCT: MILRINONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Mar 2021 07:38:06
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 Mar 2021 07:38:06
Data point term sent to Coder	System	04 Mar 2021 17:08:05
User entered 'Milrinone'	(b) (4), (b) (6)	04 Mar 2021 17:07:16

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:15:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:44
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 17:07:16

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:15:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:44
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Worsening HEart Failure'	(b) (4), (b) (6)	04 Mar 2021 17:07:16



**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:15:35**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:44
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'unknown'	(b) (4), (b) (6)	04 Mar 2021 17:07:16

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:15:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:44
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Other (OTHER)' reason for change:	(b) (4)	
Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 18:29:57
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Mar 2021 17:07:16

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:15:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:44
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Unknown' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 18:29:57
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 17:07:16

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:15:35**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:44
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:07:16

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:15:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:44
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'continuous'	(b) (4), (b) (6)	04 Mar 2021 17:07:16

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:15:35**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:44
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4), (b) (6)	04 Mar 2021 17:07:16

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:15:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:44
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 17:07:16

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:44
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:07:16



**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:44
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '0'	(b) (4), (b) (6)	04 Mar 2021 17:07:16

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:15:35**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:44
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 17:07:16

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:15:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:44
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '21 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:07:16

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:15:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:44
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 17:07:16

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:15:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:44
User entered empty.	System	04 Mar 2021 17:07:16

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:44
User entered empty.	System	04 Mar 2021 17:07:16

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:44
User entered empty.	System	04 Mar 2021 17:07:16

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:15:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
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)	04 Mar 2021 17:10:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 17:10:02
Data point term sent to Coder	System	04 Mar 2021 17:09:10
User entered 'Aspirin'	(b) (4), (b) (6)	04 Mar 2021 17:08:56



**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:15:35**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 17:08:56

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:15:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Myocardial Infarction'	(b) (4), (b) (6)	04 Mar 2021 17:08:56

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:15:35**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '325'	(b) (4), (b) (6)	04 Mar 2021 17:08:56

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:15:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Mar 2021 17:08:56

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:15:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 17:08:56

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:15:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'once (ONCE)'	(b) (4), (b) (6)	04 Mar 2021 17:08:56

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:15:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 17:08:56

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:15:35**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Mar 2021 17:08:56



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:15:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 17:08:56

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:15:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '12 Feb 2021'	(b) (4), (b) (6)	04 Mar 2021 17:08:56

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '0'	(b) (4), (b) (6)	04 Mar 2021 17:08:56

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:15:35**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 17:08:56

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:15:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '12 Feb 2021'	(b) (4), (b) (6)	04 Mar 2021 17:08:56

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:15:35**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 17:08:56

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:15:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:47
User entered empty.	System	04 Mar 2021 17:08:56

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:47
User entered empty.	System	04 Mar 2021 17:08:56



US3632075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:08:47
User entered empty.	System	04 Mar 2021 17:08:56

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:15:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 13:41:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 13:41:34
Data point term sent to Coder	System	30 Mar 2021 18:31:34
Coding entries removed.	(b) (4), (b) (6)	30 Mar 2021 18:31:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 20:56:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 20:56:03
Data point term sent to Coder	System	04 Mar 2021 17:11:12
User entered 'Furosemide'	(b) (4), (b) (6)	04 Mar 2021 17:11:02

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:15:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 17:11:02

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:15:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Myocardial Infarction'	(b) (4), (b) (6)	04 Mar 2021 17:11:02

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:15:35**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '80'	(b) (4), (b) (6)	04 Mar 2021 17:11:02

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:15:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Mar 2021 17:11:02

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:15:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 17:11:02

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:15:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'once (ONCE)'	(b) (4), (b) (6)	04 Mar 2021 17:11:02



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:15:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 17:11:02

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:15:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Intravenous (INTRAVENOUS)'	(b) (4)	
reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 18:31:31
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4), (b) (6)	04 Mar 2021 17:11:02

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:15:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 17:11:02

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '13 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:11:02

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '0'	(b) (4), (b) (6)	04 Mar 2021 17:11:02

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:15:35**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 17:11:02

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:15:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '13 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:11:02

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:15:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 17:11:02



**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:15:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:29
User entered empty.	System	04 Mar 2021 17:11:02

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:29
User entered empty.	System	04 Mar 2021 17:11:02

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:29
User entered empty.	System	04 Mar 2021 17:11:02

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:15:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: SODIUM BICARBONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 15:18:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 15:18:56
Data point term sent to Coder	System	04 Mar 2021 17:14:15
User entered 'Sodium Bicarbonate'	(b) (4), (b) (6)	04 Mar 2021 17:13:31

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:15:35**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 17:13:31

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:15:35**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'worsening renal failure'	(b) (4), (b) (6)	04 Mar 2021 17:13:31

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:15:35**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '1350'	(b) (4), (b) (6)	04 Mar 2021 17:13:31

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:15:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Mar 2021 17:13:31



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:15:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 17:13:31

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:15:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'three times daily (TID)'	(b) (4), (b) (6)	04 Mar 2021 17:13:31

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:15:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 17:13:31

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:15:35**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Mar 2021 17:13:31

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:15:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 17:13:31

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '14 Feb 2021'	(b) (4), (b) (6)	04 Mar 2021 17:13:31

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '0'	(b) (4), (b) (6)	04 Mar 2021 17:13:31

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:15:35**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 17:13:31



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:15:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '23 Feb 2021'	(b) (4), (b) (6)	04 Mar 2021 17:13:31

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:15:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 17:13:31

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:15:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:31
User entered '3'	System	04 Mar 2021 17:13:31

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:15:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:31
User entered '1'	System	04 Mar 2021 17:13:31

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:31
User entered '804 (804)'	System	04 Mar 2021 17:13:31

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:15:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Mar 2021 17:18:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 17:18:03
Data point term sent to Coder	System	04 Mar 2021 17:17:18
User entered 'carvedilol'	(b) (4), (b) (6)	04 Mar 2021 17:16:38

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:15:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 17:16:38

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:15:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'myocardial infarction'	(b) (4), (b) (6)	04 Mar 2021 17:16:38



**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:15:35**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '6.25'	(b) (4), (b) (6)	04 Mar 2021 17:16:38

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:15:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Mar 2021 17:16:38

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:15:35**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 17:16:38

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:15:35**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'twice daily (BID)'	(b) (4), (b) (6)	04 Mar 2021 17:16:38

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:15:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 17:16:38

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:15:35**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Mar 2021 17:16:38

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:15:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 17:16:38

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '14 Feb 2021'	(b) (4), (b) (6)	04 Mar 2021 17:16:38



**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '0'	(b) (4), (b) (6)	04 Mar 2021 17:16:38

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:15:35**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 17:16:38

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:15:35**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:16:38

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:15:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 17:16:38

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:15:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:36
User entered '2'	System	04 Mar 2021 17:16:38

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:15:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:36
User entered '1'	System	04 Mar 2021 17:16:38

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:36
User entered '804 (804)'	System	04 Mar 2021 17:16:38

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:15:35

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Mar 2021 17:19:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 17:19:03
Data point term sent to Coder	System	04 Mar 2021 17:18:21
User entered 'Carvedilol'	(b) (4), (b) (6)	04 Mar 2021 17:18:12



**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:15:35**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 17:18:12

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:15:35

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'myocardial infarction'	(b) (4), (b) (6)	04 Mar 2021 17:18:12

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:15:35

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '12.5'	(b) (4), (b) (6)	04 Mar 2021 17:18:12

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:15:35

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Mar 2021 17:18:12

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:15:35

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 17:18:12

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:15:35**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'twice daily (BID)'	(b) (4), (b) (6)	04 Mar 2021 17:18:12

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:15:35

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 17:18:12

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:15:35**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Mar 2021 17:18:12



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:15:35

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 17:18:12

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:15:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:18:12

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:15:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '0'	(b) (4), (b) (6)	04 Mar 2021 17:18:12

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:15:35**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Mar 2021 17:18:12

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:15:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 17:18:12

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:15:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 17:18:12

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:15:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	04 Mar 2021 17:18:12

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 17:18:12



**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Mar 2021 17:18:12

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:15:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:17:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:17:23
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	12 Apr 2021 01:34:58
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 13:23:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 13:23:34
Data point term sent to Coder	System	30 Mar 2021 18:34:36
Coding entries removed.	(b) (4), (b) (6)	30 Mar 2021 18:34:22
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 07:23:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 07:23:07
Data point term sent to Coder	System	04 Mar 2021 17:20:30
User entered 'Magnesium Sulfate'	(b) (4), (b) (6)	04 Mar 2021 17:20:17

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2849 of 3257

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:15:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 17:20:17

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:15:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Myocardial Infarction'	(b) (4), (b) (6)	04 Mar 2021 17:20:17

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:15:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '2'	(b) (4), (b) (6)	04 Mar 2021 17:20:17

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:15:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'g (g)'	(b) (4), (b) (6)	04 Mar 2021 17:20:17

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:15:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 17:20:17

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:15:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:20:17



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:15:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 17:20:17

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:15:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Intravenous (INTRAVENOUS)'	(b) (4)	
reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 18:34:22
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4), (b) (6)	04 Mar 2021 17:20:17

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:15:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 17:20:17

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:15:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '14 Feb 2021'	(b) (4), (b) (6)	04 Mar 2021 17:20:17

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:15:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '0'	(b) (4), (b) (6)	04 Mar 2021 17:20:17

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:15:35**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 17:20:17

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:15:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '14 Feb 2021'	(b) (4), (b) (6)	04 Mar 2021 17:20:17

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:15:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 17:20:17



**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:15:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:47
User entered empty.	System	04 Mar 2021 17:20:17

US3632075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:47
User entered empty.	System	04 Mar 2021 17:20:17

US3632075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:47
User entered empty.	System	04 Mar 2021 17:20:17

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:15:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: VASOPROTECTIVES, ATC: ANTIVARICOSE THERAPY, ATC: HEPARINS OR HEPARINOIDS FOR TOPICAL USE, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Mar 2021 20:59:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 20:59:09
Data point term sent to Coder	System	04 Mar 2021 17:25:38
User entered 'Heparin'	(b) (4), (b) (6)	04 Mar 2021 17:24:51

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:15:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:49
User signature succeeded.	Colleen Kelley (b) (4)	28 Apr 2021 22:19:03
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 21:33:30
User closed query 'This is checked as yes in the source; please verify and update the source/EDC.' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 21:33:11
Query 'This is checked as yes in the source; please verify and update the source/EDC.' answered with 'updated' (Site from CRA).	Christina Bacher (b) (4)	22 Apr 2021 20:29:11
Signature has been broken.	Christina Bacher (b) (4)	22 Apr 2021 20:28:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Christina Bacher (b) (4)	22 Apr 2021 20:28:34
User opened query 'This is checked as yes in the source; please verify and update the source/EDC.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 20:20:03
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 20:19:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User closed query 'PER CDM: Kindly confirm the response for Prophylaxis as indication is Myocardial Infarction.Kindly review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 09:47:29
Query 'PER CDM: Kindly confirm the response for Prophylaxis as indication is Myocardial Infarction.Kindly review and update accordingly.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 17:28:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 17:28:34
User opened query 'PER CDM: Kindly confirm the response for Prophylaxis as indication is Myocardial Infarction.Kindly review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 05:36:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Mar 2021 17:24:51

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:15:35**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'myocardial infarction'	(b) (4), (b) (6)	04 Mar 2021 17:24:51

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:15:35**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'unknown'	(b) (4), (b) (6)	04 Mar 2021 17:24:51

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:15:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	04 Mar 2021 17:25:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Mar 2021 17:25:39
User entered 'Other (OTHER)' reason for change:	(b) (4), (b) (6)	04 Mar 2021 17:25:39
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Mar 2021 17:24:51
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 17:24:51



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:15:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Unknown' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 18:36:00
User entered 'units' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:25:39
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 17:24:51

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:15:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'other (OTHER)'	(b) (4), (b) (6)	04 Mar 2021 17:24:51

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:15:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'continuous drip (frequent titration)'	(b) (4), (b) (6)	04 Mar 2021 17:24:51

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:15:35**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4), (b) (6)	04 Mar 2021 17:24:51

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:15:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 17:24:51

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '13 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:24:51

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '0'	(b) (4), (b) (6)	04 Mar 2021 17:24:51

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:15:35**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 17:24:51



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:15:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '22 Feb 2021'	(b) (4), (b) (6)	04 Mar 2021 17:24:51

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:15:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 17:24:51

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:15:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:49
User entered empty.	System	04 Mar 2021 17:24:51

US3632075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:49
User entered empty.	System	04 Mar 2021 17:24:51

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:49
User entered empty.	System	04 Mar 2021 17:24:51

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:15:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Mar 2021 20:57:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 20:57:03
Data point term sent to Coder	System	04 Mar 2021 17:27:42
User entered 'Furosemide'	(b) (4), (b) (6)	04 Mar 2021 17:27:24

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:15:35**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 17:27:24

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:15:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'worsening renal failure'	(b) (4), (b) (6)	04 Mar 2021 17:27:24



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:15:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '40'	(b) (4), (b) (6)	04 Mar 2021 17:27:24

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:15:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Mar 2021 17:27:24

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:15:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 17:27:24

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:15:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'twice daily (BID)'	(b) (4), (b) (6)	04 Mar 2021 17:27:24

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:15:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 17:27:24

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:15:35**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Mar 2021 17:27:24

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:15:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 17:27:24

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:15:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '14 Feb 2021'	(b) (4), (b) (6)	04 Mar 2021 17:27:24



**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '0'	(b) (4), (b) (6)	04 Mar 2021 17:27:24

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:15:35**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 17:27:24

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:15:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '22 Feb 2021'	(b) (4), (b) (6)	04 Mar 2021 17:27:24

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:15:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 17:27:24

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:15:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:53
User entered '2'	System	04 Mar 2021 17:27:24

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:53
User entered '1'	System	04 Mar 2021 17:27:24

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:53
User entered '804 (804)'	System	04 Mar 2021 17:27:24

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:15:35

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: TORASEMIDE, PRODUCTSYNONYM: TORSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 17:35:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 17:35:03
Data point term sent to Coder	System	04 Mar 2021 17:33:48
User entered 'Torsemide'	(b) (4), (b) (6)	04 Mar 2021 17:33:03



**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:15:35**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 17:33:03

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:15:35

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'worsening renal failure'	(b) (4), (b) (6)	04 Mar 2021 17:33:03

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:15:35**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '10'	(b) (4), (b) (6)	04 Mar 2021 17:33:03

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:15:35

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Mar 2021 17:33:03

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:15:35

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 17:33:03

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:15:35**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'once daily (QD)'	(b) (4), (b) (6)	04 Mar 2021 17:33:03

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:15:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:33:03

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:15:35**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Mar 2021 17:33:03



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:15:35

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:33:03

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:15:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '27 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:33:03

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '0'	(b) (4), (b) (6)	04 Mar 2021 17:33:03

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:15:35**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Mar 2021 17:33:03

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:15:35**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 17:33:03

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:15:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 17:33:03

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:15:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 17:33:03

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 17:33:03



**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Mar 2021 17:33:03

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:15:35

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: ISOSORBIDE DINITRATE, PRODUCTSYNONYM: ISORDIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Mar 2021 10:28:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Mar 2021 10:28:48
Data point term sent to Coder	System	15 Mar 2021 18:16:43
User entered 'Isordil'	(b) (4), (b) (6)	15 Mar 2021 18:15:43

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:15:35**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	15 Mar 2021 18:15:43

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:15:35**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Worsening Heart Failure (AE)'	(b) (4), (b) (6)	15 Mar 2021 18:15:43

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:15:35

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '30'	(b) (4), (b) (6)	15 Mar 2021 18:15:43

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:15:35

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Mar 2021 18:15:43

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:15:35**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 18:15:43

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:15:35**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'twice daily (BID)'	(b) (4), (b) (6)	15 Mar 2021 18:15:43



**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:15:35**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 18:15:43

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:15:35**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	15 Mar 2021 18:15:43

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:15:35

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 18:15:43

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:15:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '03 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:15:43

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '0'	(b) (4), (b) (6)	15 Mar 2021 18:15:43

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:15:35

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 10:13:52
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'Medication is continuing despite AE ending' (Site from DM).	Isaac Perez (b) (4)	05 Apr 2021 19:37:06
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 03:40:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Mar 2021 18:15:43

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:15:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 18:15:43

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:15:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	15 Mar 2021 18:15:43



**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:15:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	15 Mar 2021 18:15:43

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Mar 2021 18:15:43

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Mar 2021 18:15:43

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:15:35

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: HYDRAZINOPHTHALAZINE DERIVATIVES, PRODUCT: HYDRALAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Mar 2021 09:41:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Mar 2021 09:41:48
Data point term sent to Coder	System	15 Mar 2021 18:16:43
User entered 'Hydralazine'	(b) (4), (b) (6)	15 Mar 2021 18:16:30

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:15:35**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	15 Mar 2021 18:16:30

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:15:35**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Worsening Heart Failure (AE)'	(b) (4), (b) (6)	15 Mar 2021 18:16:30

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:15:35

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '75'	(b) (4), (b) (6)	15 Mar 2021 18:16:30

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:15:35

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Mar 2021 18:16:30



**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:15:35**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 18:16:30

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:15:35

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'twice daily (BID)'	(b) (4), (b) (6)	15 Mar 2021 18:16:30

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:15:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:16:30

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:15:35**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	15 Mar 2021 18:16:30

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:15:35

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:16:30

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '03 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:16:30

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '0'	(b) (4), (b) (6)	15 Mar 2021 18:16:30

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:15:35

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 10:14:12
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'Medication is ongoing past date of AE end' (Site from DM).	Isaac Perez (b) (4)	05 Apr 2021 19:37:25
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 03:40:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Mar 2021 18:16:30



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:15:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 18:16:30

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:15:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:16:30

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:15:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	15 Mar 2021 18:16:30

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Mar 2021 18:16:30

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Mar 2021 18:16:30

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:15:35

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: DRUGS FOR TREATMENT OF HYPERKALEMIA AND HYPERPHOSPHATEMIA, PRODUCT: PATIROMER - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Mar 2021 10:01:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Mar 2021 10:01:48
Data point term sent to Coder	System	15 Mar 2021 18:17:44
User entered 'Patiromer'	(b) (4), (b) (6)	15 Mar 2021 18:17:02

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:15:35**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	15 Mar 2021 18:17:02

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:15:35**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Worsening Renal Failure (AE)'	(b) (4), (b) (6)	15 Mar 2021 18:17:02



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:15:35

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '16.8'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:17:02

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:15:35**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'g (g)'	(b) (4), (b) (6)	15 Mar 2021 18:17:02

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:15:35**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:17:02

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:15:35**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'as needed (PRN)'	(b) (4), (b) (6)	15 Mar 2021 18:17:02

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:15:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:17:02

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:15:35**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	15 Mar 2021 18:17:02

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:15:35

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:17:02

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '03 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:17:02



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:15:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '0'	(b) (4), (b) (6)	15 Mar 2021 18:17:02

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:15:35

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 10:14:16
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'Medication continuation despite end of AE' (Site from DM).	Isaac Perez (b) (4)	05 Apr 2021 19:38:17
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 03:40:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Mar 2021 18:17:02

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:15:35**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 18:17:02

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:15:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Mar 2021 18:17:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Mar 2021 18:17:11
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 18:17:11
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 18:17:02
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 18:17:02

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:15:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Mar 2021 18:17:02

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Mar 2021 18:17:02

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Mar 2021 18:17:02

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:15:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: ACICLOVIR, PRODUCTSYNONYM: ACYCLOVIR [ACICLOVIR] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 18:55:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 18:55:09
Data point term sent to Coder	System	30 Mar 2021 18:53:59
User entered 'Acyclovir'	(b) (4), (b) (6)	30 Mar 2021 18:53:50



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:15:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 18:53:50

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:15:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
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) (4), (b) (6)	08 Apr 2021 08:07:02
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 condition to MH' (Site from DM).	Isaac Perez (b) (4) (b) (4)	07 Apr 2021 17:19:55
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).	(b) (4), (b) (6)	06 Apr 2021 09:34:57
User entered 'Herpes Zoster'	(b) (4), (b) (6)	30 Mar 2021 18:53:50

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:15:35**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '200'	(b) (4), (b) (6)	30 Mar 2021 18:53:50

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:15:35**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'mg (mg)'	(b) (4), (b) (6)	30 Mar 2021 18:53:50

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:15:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:53:50

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:15:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'three times daily (TID)'	(b) (4), (b) (6)	30 Mar 2021 18:53:50

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:15:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:53:50

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:15:35**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	30 Mar 2021 18:53:50



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:15:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:53:50

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '01 Sep 2020'	(b) (4), (b) (6)	30 Mar 2021 18:53:50

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '0'	(b) (4), (b) (6)	30 Mar 2021 18:53:50

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:15:35**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:53:50

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:15:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '30 Dec 2020'	(b) (4), (b) (6)	30 Mar 2021 18:53:50

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:15:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 18:53:50

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:15:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:10
User entered '3'	System	30 Mar 2021 18:53:50

US3632075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:10
User entered '1'	System	30 Mar 2021 18:53:50



**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:10
User entered '804 (804)'	System	30 Mar 2021 18:53:50

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:15:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:13
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	31 Mar 2021 07:58:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 07:58:26
Data point term sent to Coder	System	30 Mar 2021 18:57:02
User entered 'Lasix'	(b) (4), (b) (6)	30 Mar 2021 18:56:40

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:15:35**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:13
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 18:56:40

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:15:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:13
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Left leg amputation'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:56:40

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:15:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:13
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '40'	(b) (4), (b) (6)	30 Mar 2021 18:56:40

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:15:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:13
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'mg (mg)'	(b) (4), (b) (6)	30 Mar 2021 18:56:40

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:15:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:13
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:56:40

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:15:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:13
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:56:40



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:15:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:13
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:56:40

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:15:35**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:13
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	30 Mar 2021 18:56:40

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:15:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:13
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:56:40

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:15:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:13
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:56:40

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:15:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:13
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '0'	(b) (4), (b) (6)	30 Mar 2021 18:56:40

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:15:35**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:13
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 18:56:40

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:15:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:13
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:56:40

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:15:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:13
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 18:56:40



**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:15:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:13
User entered '2'	System	30 Mar 2021 18:56:40

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:13
User entered '1'	System	30 Mar 2021 18:56:40

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:13
User entered '804 (804)'	System	30 Mar 2021 18:56:40

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:15:35

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: VITAMIN K ANTAGONISTS, PRODUCT: WARFARIN SODIUM, PRODUCTSYNONYM: COUMADIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 18:41:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 18:41:22
Data point term sent to Coder	System	05 Apr 2021 18:40:34
User entered 'Coumadin'	Isaac Perez (b) (4)	05 Apr 2021 18:40:29

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:15:35

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	Isaac Perez (b) (4)	05 Apr 2021 18:40:29

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:15:35

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Atrial Fibrillation'	Isaac Perez (b) (4)	05 Apr 2021 18:40:29

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:15:35

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '5'	Isaac Perez (b) (4)	05 Apr 2021 18:40:29

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:15:35

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'mg (mg)'	Isaac Perez (b) (4)	05 Apr 2021 18:40:29



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:15:35

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Isaac Perez (b) (4)	05 Apr 2021 18:40:29

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:15:35

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'other (OTHER)'	Isaac Perez (b) (4)	05 Apr 2021 18:40:29

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:15:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Wednesdays, Saturdays, and Sundays'	Isaac Perez (b) (4)	05 Apr 2021 18:40:29

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:15:35**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Oral (ORAL)'	Isaac Perez (b) (4)	05 Apr 2021 18:40:29

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:15:35

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Isaac Perez (b) (4)	05 Apr 2021 18:40:29

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:15:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '03 Mar 2021'	Isaac Perez (b) (4)	05 Apr 2021 18:40:29

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:15:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered '0'	Isaac Perez (b) (4)	05 Apr 2021 18:40:29

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:15:35**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'Yes (Y)'	Isaac Perez (b) (4)	05 Apr 2021 18:40:29



US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:15:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered empty.	Isaac Perez (b) (4)	05 Apr 2021 18:40:29

US3632075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:15:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
User entered 'No (N)'	Isaac Perez (b) (4)	05 Apr 2021 18:40:29

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:15:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 18:40:29

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 18:40:29

**US3632075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:15:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 18:40:29

US3632075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:15:35

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:04:21
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:23:40
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	24 Feb 2021 19:22:10
User entered 'No (N)'	Sarah Wiatrek (b) (4)	08 Feb 2021 20:53:37

US3632075

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:24:43
User entered '12 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 19:24:26

US3632075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:15:35

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:24:43
User entered 'Portable Chest xray- 1 view'	(b) (4), (b) (6)	24 Feb 2021 19:24:26



US3632075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:15:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:24:43
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	24 Feb 2021 19:24:26

US3632075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:15:35

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:24:43
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 19:24:26

US3632075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:15:35

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:02:31
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:24:45
User entered '13 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 19:25:07

US3632075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:15:35

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:02:31
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:24:45
User entered 'CT Chest without contrast'	(b) (4), (b) (6)	24 Feb 2021 19:25:07

US3632075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:15:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:02:31
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:24:45
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	24 Feb 2021 19:25:07

US3632075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:15:35

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:02:31
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:24:45
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 19:25:07

US3632075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:15:35

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:02:35
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:24:47
User entered '13 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 19:25:55

US3632075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:15:35

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:02:35
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:24:47
User entered 'CT abdomen and pelvis without IV contrast'	(b) (4), (b) (6)	24 Feb 2021 19:25:55



**US3632075**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 09:15:35**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:02:35
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:24:47
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	24 Feb 2021 19:25:55

US3632075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:15:35

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:02:35
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:24:47
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 19:25:55

US3632075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:15:35

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:02:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:16:00
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
User entered '12 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 19:26:32

**US3632075**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 10 Jun 2021 09:15:35**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:02:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:16:00
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
User entered '12 Lead EKG'	(b) (4), (b) (6)	24 Feb 2021 19:26:32

US3632075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:15:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:02:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:16:00
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	24 Feb 2021 19:26:32

US3632075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:15:35

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:02:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:16:00
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 19:26:32

**US3632075**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (5)**

**Generated On: 10 Jun 2021 09:15:35**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:02:42
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:16:07
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
User entered '13 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 19:26:54

US3632075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:15:35

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:02:42
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:16:07
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
User entered '12-LEAD EKG' reason for change:	(b) (4)	
Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 19:41:35
User entered '12-lead AKG'	(b) (4), (b) (6)	24 Feb 2021 19:26:54



US3632075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:15:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:02:42
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:16:07
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
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	24 Feb 2021 19:41:35
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	System	24 Feb 2021 19:41:35
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	24 Feb 2021 19:41:35
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 19:26:54

**US3632075**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (5)**

**Generated On: 10 Jun 2021 09:15:35**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:02:42
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:16:07
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 19:26:54

US3632075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:15:35

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:02:47
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:16:17
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
User entered '14 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 19:28:01

US3632075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:15:35

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:02:47
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:16:17
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
User entered 'Transthoracic echocardiogram'	(b) (4), (b) (6)	24 Feb 2021 19:28:01

US3632075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:15:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:02:47
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:16:17
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	24 Feb 2021 19:28:01

US3632075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:15:35

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:02:47
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:16:17
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 19:28:01

**US3632075**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (7)**

**Generated On: 10 Jun 2021 09:15:35**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:02:51
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:16:35
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
User entered '17 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 19:40:13

US3632075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:15:35

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:02:51
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:16:35
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
User entered 'Right Heart Catheterization'	(b) (4), (b) (6)	24 Feb 2021 19:40:13



US3632075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:15:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:02:51
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:16:35
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	24 Feb 2021 19:40:13

US3632075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:15:35

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:02:51
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:16:35
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 19:40:13

US3632075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:15:35

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:02:55
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:16:42
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
User entered '23 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 20:00:24

US3632075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:15:35

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:02:55
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:16:42
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
User entered 'Transthoracic Echocardiogram'	(b) (4), (b) (6)	24 Feb 2021 20:00:24

US3632075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:15:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:02:55
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:16:42
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	24 Feb 2021 20:00:24

US3632075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:15:35

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:02:55
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:16:42
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:13:39
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 20:00:24

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered	System	23 Feb 2021 16:39:43
'USA-US120-2021-MRNA-1273-P301000004'		

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43



**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'No (N)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'No (N)'	System	23 Feb 2021 16:39:43

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 19:19:16
Un-reviewed for Safety.	System	25 Feb 2021 19:18:03
User entered 'Yes (Y)'	System	25 Feb 2021 19:18:03
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'No (N)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Colleen'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Kelley'	System	23 Feb 2021 16:39:43



US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:55:46
User closed query 'Please enter address.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 16:55:34
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:48:43
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
Un-reviewed for Safety.	System	29 Mar 2021 15:29:21
User entered empty.	System	29 Mar 2021 15:29:21
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:46
Query 'Please enter address.' answered with 'updated' (Site from CRA).	Bezuayehu Mandefro (b) (4)	26 Mar 2021 13:03:04
User entered '68 Armstrong St'	Bezuayehu Mandefro (b) (4)	26 Mar 2021 13:02:49
User opened query 'Please enter address.' (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 20:05:23

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:56:32
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:48:43
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	29 Mar 2021 15:29:21
Reviewed for Safety.	System	29 Mar 2021 15:29:21
	(b) (4), (b) (6)	29 Mar 2021 15:28:46
User entered 'Atlanta'	Bezuayehu Mandefro	26 Mar 2021 13:02:49
	(b) (4)	

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'GA'	System	23 Feb 2021 16:39:43

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:57:25
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:48:43
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	29 Mar 2021 15:29:21
Reviewed for Safety.	System	29 Mar 2021 15:29:21
	(b) (4), (b) (6)	29 Mar 2021 15:28:46
User entered '30303'	Bezuayehu Mandefro	26 Mar 2021 13:02:49
	(b) (4)	

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 19:19:16
User entered 'US'	System	23 Feb 2021 16:42:14

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	23 Apr 2021 14:43:34
User entered '9'	System	21 Apr 2021 12:56:35
User entered '8'	System	06 Apr 2021 14:49:03
User entered '7'	System	30 Mar 2021 18:47:41
User entered '6'	System	29 Mar 2021 15:29:21
User entered '5'	System	22 Mar 2021 13:28:07
User entered '4'	System	19 Mar 2021 13:03:00
User entered '3'	System	16 Mar 2021 13:25:27
User entered '2'	System	25 Feb 2021 19:19:33
User entered '1'	System	23 Feb 2021 16:42:14

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered		
'USA-US120-2021-MRNA-1273-P301000004'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43



**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'No (N)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'No (N)'	System	23 Feb 2021 16:39:43

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 19:19:16
Un-reviewed for Safety.	System	25 Feb 2021 19:18:03
User entered 'Yes (Y)'	System	25 Feb 2021 19:18:03
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'No (N)'	System	23 Feb 2021 16:39:43

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Colleen'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Kelley'	System	23 Feb 2021 16:39:43



US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:55:46
User closed query 'Please enter address.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 16:55:34
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:48:43
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
Un-reviewed for Safety.	System	29 Mar 2021 15:29:21
User entered empty.	System	29 Mar 2021 15:29:21
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:46
Query 'Please enter address.' answered with 'updated' (Site from CRA).	Bezuayehu Mandefro (b) (4)	26 Mar 2021 13:03:04
User entered '68 Armstrong St'	Bezuayehu Mandefro (b) (4)	26 Mar 2021 13:02:49
User opened query 'Please enter address.' (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 20:05:23

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:56:32
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:48:43
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	29 Mar 2021 15:29:21
Reviewed for Safety.	System	29 Mar 2021 15:29:21
	(b) (4), (b) (6)	29 Mar 2021 15:28:46
User entered 'Atlanta'	Bezuayehu Mandefro	26 Mar 2021 13:02:49
	(b) (4)	

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'GA'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:57:25
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:48:43
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	29 Mar 2021 15:29:21
Reviewed for Safety.	System	29 Mar 2021 15:29:21
	(b) (4), (b) (6)	29 Mar 2021 15:28:46
User entered '30303'	Bezuayehu Mandefro	26 Mar 2021 13:02:49
	(b) (4)	

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 19:19:16
User entered 'US'	System	23 Feb 2021 16:42:14

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	23 Apr 2021 14:43:34
User entered '9'	System	21 Apr 2021 12:56:35
User entered '8'	System	06 Apr 2021 14:49:03
User entered '7'	System	30 Mar 2021 18:47:41
User entered '6'	System	29 Mar 2021 15:29:21
User entered '5'	System	22 Mar 2021 13:28:07
User entered '4'	System	19 Mar 2021 13:03:00
User entered '3'	System	16 Mar 2021 13:25:27
User entered '2'	System	25 Feb 2021 19:19:33
User entered '1'	System	23 Feb 2021 16:42:14

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:15:35**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:04:58
User entered '23/Feb/2021 16:42'	System	23 Feb 2021 16:42:14

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:15:35

**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.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 19:19:16
User entered 'I'	(b) (4), (b) (6)	23 Feb 2021 16:42:14



**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered		
'USA-US120-2021-MRNA-1273-P301000004'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'No (N)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'No (N)'	System	23 Feb 2021 16:39:43

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 19:19:16
Un-reviewed for Safety.	System	25 Feb 2021 19:18:03
User entered 'Yes (Y)'	System	25 Feb 2021 19:18:03
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'No (N)'	System	23 Feb 2021 16:39:43



**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Colleen'	System	23 Feb 2021 16:39:43

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Kelley'	System	23 Feb 2021 16:39:43

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:55:46
User closed query 'Please enter address.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 16:55:34
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:48:43
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
Un-reviewed for Safety.	System	29 Mar 2021 15:29:21
User entered empty.	System	29 Mar 2021 15:29:21
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:46
Query 'Please enter address.' answered with 'updated' (Site from CRA).	Bezuayehu Mandefro (b) (4)	26 Mar 2021 13:03:04
User entered '68 Armstrong St'	Bezuayehu Mandefro (b) (4)	26 Mar 2021 13:02:49
User opened query 'Please enter address.' (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 20:05:23

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:56:32
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:48:43
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	29 Mar 2021 15:29:21
Reviewed for Safety.	System	29 Mar 2021 15:29:21
	(b) (4), (b) (6)	29 Mar 2021 15:28:46
User entered 'Atlanta'	Bezuayehu Mandefro	26 Mar 2021 13:02:49
	(b) (4)	

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'GA'	System	23 Feb 2021 16:39:43

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:57:25
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:48:43
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	29 Mar 2021 15:29:21
Reviewed for Safety.	System	29 Mar 2021 15:29:21
	(b) (4), (b) (6)	29 Mar 2021 15:28:46
User entered '30303'	Bezuayehu Mandefro	26 Mar 2021 13:02:49
	(b) (4)	

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 19:19:16
User entered 'US'	System	23 Feb 2021 16:42:14

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	23 Apr 2021 14:43:34
User entered '9'	System	21 Apr 2021 12:56:35
User entered '8'	System	06 Apr 2021 14:49:03
User entered '7'	System	30 Mar 2021 18:47:41
User entered '6'	System	29 Mar 2021 15:29:21
User entered '5'	System	22 Mar 2021 13:28:07
User entered '4'	System	19 Mar 2021 13:03:00
User entered '3'	System	16 Mar 2021 13:25:27
User entered '2'	System	25 Feb 2021 19:19:33
User entered '1'	System	23 Feb 2021 16:42:14



**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:15:35**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:04:58
User entered '25/Feb/2021 13:19'	System	25 Feb 2021 19:19:33

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:15:35

**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.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 13:25:05
User entered 'I'	(b) (4), (b) (6)	25 Feb 2021 19:19:33

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered		
'USA-US120-2021-MRNA-1273-P301000004'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'No (N)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43



**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'No (N)'	System	23 Feb 2021 16:39:43

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 19:19:16
Un-reviewed for Safety.	System	25 Feb 2021 19:18:03
User entered 'Yes (Y)'	System	25 Feb 2021 19:18:03
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'No (N)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Colleen'	System	23 Feb 2021 16:39:43

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Kelley'	System	23 Feb 2021 16:39:43

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:55:46
User closed query 'Please enter address.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 16:55:34
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:48:43
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
Un-reviewed for Safety.	System	29 Mar 2021 15:29:21
User entered empty.	System	29 Mar 2021 15:29:21
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:46
Query 'Please enter address.' answered with 'updated' (Site from CRA).	Bezuayehu Mandefro (b) (4)	26 Mar 2021 13:03:04
User entered '68 Armstrong St'	Bezuayehu Mandefro (b) (4)	26 Mar 2021 13:02:49
User opened query 'Please enter address.' (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 20:05:23

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:56:32
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:48:43
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	29 Mar 2021 15:29:21
Reviewed for Safety.	System	29 Mar 2021 15:29:21
	(b) (4), (b) (6)	29 Mar 2021 15:28:46
User entered 'Atlanta'	Bezuayehu Mandefro	26 Mar 2021 13:02:49
	(b) (4)	

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'GA'	System	23 Feb 2021 16:39:43

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:57:25
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:48:43
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	29 Mar 2021 15:29:21
Reviewed for Safety.	System	29 Mar 2021 15:29:21
	(b) (4), (b) (6)	29 Mar 2021 15:28:46
User entered '30303'	Bezuayehu Mandefro	26 Mar 2021 13:02:49
	(b) (4)	



**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 19:19:16
User entered 'US'	System	23 Feb 2021 16:42:14

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	23 Apr 2021 14:43:34
User entered '9'	System	21 Apr 2021 12:56:35
User entered '8'	System	06 Apr 2021 14:49:03
User entered '7'	System	30 Mar 2021 18:47:41
User entered '6'	System	29 Mar 2021 15:29:21
User entered '5'	System	22 Mar 2021 13:28:07
User entered '4'	System	19 Mar 2021 13:03:00
User entered '3'	System	16 Mar 2021 13:25:27
User entered '2'	System	25 Feb 2021 19:19:33
User entered '1'	System	23 Feb 2021 16:42:14

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 09:15:35**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:04:58
User entered '16/Mar/2021 08:25'	System	16 Mar 2021 13:25:27

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:15:35

**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.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	29 Mar 2021 15:28:46
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:04:58
User entered 'I'	(b) (4), (b) (6)	16 Mar 2021 13:25:27

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered		
'USA-US120-2021-MRNA-1273-P301000004'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'No (N)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43



**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'No (N)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 19:19:16
Un-reviewed for Safety.	System	25 Feb 2021 19:18:03
User entered 'Yes (Y)'	System	25 Feb 2021 19:18:03
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'No (N)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Colleen'	System	23 Feb 2021 16:39:43

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Kelley'	System	23 Feb 2021 16:39:43

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:55:46
User closed query 'Please enter address.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 16:55:34
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:48:43
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
Un-reviewed for Safety.	System	29 Mar 2021 15:29:21
User entered empty.	System	29 Mar 2021 15:29:21
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:46
Query 'Please enter address.' answered with 'updated' (Site from CRA).	Bezuayehu Mandefro (b) (4)	26 Mar 2021 13:03:04
User entered '68 Armstrong St'	Bezuayehu Mandefro (b) (4)	26 Mar 2021 13:02:49
User opened query 'Please enter address.' (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 20:05:23

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:56:32
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:48:43
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	29 Mar 2021 15:29:21
Reviewed for Safety.	System	29 Mar 2021 15:29:21
	(b) (4), (b) (6)	29 Mar 2021 15:28:46
User entered 'Atlanta'	Bezuayehu Mandefro	26 Mar 2021 13:02:49
	(b) (4)	



**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'GA'	System	23 Feb 2021 16:39:43

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:57:25
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:48:43
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	29 Mar 2021 15:29:21
Reviewed for Safety.	System	29 Mar 2021 15:29:21
	(b) (4), (b) (6)	29 Mar 2021 15:28:46
User entered '30303'	Bezuayehu Mandefro	26 Mar 2021 13:02:49
	(b) (4)	

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 19:19:16
User entered 'US'	System	23 Feb 2021 16:42:14

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	23 Apr 2021 14:43:34
User entered '9'	System	21 Apr 2021 12:56:35
User entered '8'	System	06 Apr 2021 14:49:03
User entered '7'	System	30 Mar 2021 18:47:41
User entered '6'	System	29 Mar 2021 15:29:21
User entered '5'	System	22 Mar 2021 13:28:07
User entered '4'	System	19 Mar 2021 13:03:00
User entered '3'	System	16 Mar 2021 13:25:27
User entered '2'	System	25 Feb 2021 19:19:33
User entered '1'	System	23 Feb 2021 16:42:14

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 09:15:35**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:04:58
User entered '19/Mar/2021 09:02'	System	19 Mar 2021 13:03:00

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:15:35

**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.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	29 Mar 2021 15:28:46
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:04:58
User entered 'I'	(b) (4), (b) (6)	19 Mar 2021 13:03:00

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered		
'USA-US120-2021-MRNA-1273-P301000004'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43



**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'No (N)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'No (N)'	System	23 Feb 2021 16:39:43

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 19:19:16
Un-reviewed for Safety.	System	25 Feb 2021 19:18:03
User entered 'Yes (Y)'	System	25 Feb 2021 19:18:03
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'No (N)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Colleen'	System	23 Feb 2021 16:39:43

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Kelley'	System	23 Feb 2021 16:39:43



US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:55:46
User closed query 'Please enter address.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 16:55:34
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:48:43
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
Un-reviewed for Safety.	System	29 Mar 2021 15:29:21
User entered empty.	System	29 Mar 2021 15:29:21
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:46
Query 'Please enter address.' answered with 'updated' (Site from CRA).	Bezuayehu Mandefro (b) (4)	26 Mar 2021 13:03:04
User entered '68 Armstrong St'	Bezuayehu Mandefro (b) (4)	26 Mar 2021 13:02:49
User opened query 'Please enter address.' (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 20:05:23

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:56:32
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:48:43
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	29 Mar 2021 15:29:21
Reviewed for Safety.	System	29 Mar 2021 15:29:21
	(b) (4), (b) (6)	29 Mar 2021 15:28:46
User entered 'Atlanta'	Bezuayehu Mandefro	26 Mar 2021 13:02:49
	(b) (4)	

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'GA'	System	23 Feb 2021 16:39:43

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:57:25
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:48:43
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	29 Mar 2021 15:29:21
Reviewed for Safety.	System	29 Mar 2021 15:29:21
	(b) (4), (b) (6)	29 Mar 2021 15:28:46
User entered '30303'	Bezuayehu Mandefro	26 Mar 2021 13:02:49
	(b) (4)	

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 19:19:16
User entered 'US'	System	23 Feb 2021 16:42:14

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	23 Apr 2021 14:43:34
User entered '9'	System	21 Apr 2021 12:56:35
User entered '8'	System	06 Apr 2021 14:49:03
User entered '7'	System	30 Mar 2021 18:47:41
User entered '6'	System	29 Mar 2021 15:29:21
User entered '5'	System	22 Mar 2021 13:28:07
User entered '4'	System	19 Mar 2021 13:03:00
User entered '3'	System	16 Mar 2021 13:25:27
User entered '2'	System	25 Feb 2021 19:19:33
User entered '1'	System	23 Feb 2021 16:42:14

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (5)**

**Generated On: 10 Jun 2021 09:15:35**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:04:58
User entered '22/Mar/2021 06:28'	System	22 Mar 2021 13:28:07

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:15:35

**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.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	29 Mar 2021 15:28:46
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:04:58
User entered 'I'	(b) (4), (b) (6)	22 Mar 2021 13:28:07



**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered		
'USA-US120-2021-MRNA-1273-P301000004'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'No (N)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'No (N)'	System	23 Feb 2021 16:39:43

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 19:19:16
Un-reviewed for Safety.	System	25 Feb 2021 19:18:03
User entered 'Yes (Y)'	System	25 Feb 2021 19:18:03
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'No (N)'	System	23 Feb 2021 16:39:43



**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Colleen'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Kelley'	System	23 Feb 2021 16:39:43

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:55:46
User closed query 'Please enter address.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 16:55:34
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:48:43
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
Un-reviewed for Safety.	System	29 Mar 2021 15:29:21
User entered empty.	System	29 Mar 2021 15:29:21
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:46
Query 'Please enter address.' answered with 'updated' (Site from CRA).	Bezuayehu Mandefro (b) (4)	26 Mar 2021 13:03:04
User entered '68 Armstrong St'	Bezuayehu Mandefro (b) (4)	26 Mar 2021 13:02:49
User opened query 'Please enter address.' (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 20:05:23

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:56:32
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:48:43
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	29 Mar 2021 15:29:21
Reviewed for Safety.	System	29 Mar 2021 15:29:21
	(b) (4), (b) (6)	29 Mar 2021 15:28:46
User entered 'Atlanta'	Bezuayehu Mandefro	26 Mar 2021 13:02:49
	(b) (4)	

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'GA'	System	23 Feb 2021 16:39:43

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:57:25
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:48:43
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	29 Mar 2021 15:29:21
Reviewed for Safety.	System	29 Mar 2021 15:29:21
	(b) (4), (b) (6)	29 Mar 2021 15:28:46
User entered '30303'	Bezuayehu Mandefro	26 Mar 2021 13:02:49
	(b) (4)	

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 19:19:16
User entered 'US'	System	23 Feb 2021 16:42:14

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	23 Apr 2021 14:43:34
User entered '9'	System	21 Apr 2021 12:56:35
User entered '8'	System	06 Apr 2021 14:49:03
User entered '7'	System	30 Mar 2021 18:47:41
User entered '6'	System	29 Mar 2021 15:29:21
User entered '5'	System	22 Mar 2021 13:28:07
User entered '4'	System	19 Mar 2021 13:03:00
User entered '3'	System	16 Mar 2021 13:25:27
User entered '2'	System	25 Feb 2021 19:19:33
User entered '1'	System	23 Feb 2021 16:42:14



**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (6)**

**Generated On: 10 Jun 2021 09:15:35**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:57:25
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
User entered '29/Mar/2021 11:29'	(b) (4) System	29 Mar 2021 15:29:21

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:15:35

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:57:25
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:48:43
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
User entered 'I'	(b) (4), (b) (6)	29 Mar 2021 15:29:21

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered	System	23 Feb 2021 16:39:43
'USA-US120-2021-MRNA-1273-P301000004'		

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'No (N)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43



**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'No (N)'	System	23 Feb 2021 16:39:43

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 19:19:16
Un-reviewed for Safety.	System	25 Feb 2021 19:18:03
User entered 'Yes (Y)'	System	25 Feb 2021 19:18:03
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'No (N)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Colleen'	System	23 Feb 2021 16:39:43

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Kelley'	System	23 Feb 2021 16:39:43

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:55:46
User closed query 'Please enter address.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 16:55:34
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:48:43
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
Un-reviewed for Safety.	System	29 Mar 2021 15:29:21
User entered empty.	System	29 Mar 2021 15:29:21
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:46
Query 'Please enter address.' answered with 'updated' (Site from CRA).	Bezuayehu Mandefro (b) (4)	26 Mar 2021 13:03:04
User entered '68 Armstrong St'	Bezuayehu Mandefro (b) (4)	26 Mar 2021 13:02:49
User opened query 'Please enter address.' (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 20:05:23

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:56:32
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:48:43
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	29 Mar 2021 15:29:21
Reviewed for Safety.	System	29 Mar 2021 15:29:21
	(b) (4), (b) (6)	29 Mar 2021 15:28:46
User entered 'Atlanta'	Bezuayehu Mandefro	26 Mar 2021 13:02:49
	(b) (4)	

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'GA'	System	23 Feb 2021 16:39:43

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:57:25
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:48:43
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	29 Mar 2021 15:29:21
Reviewed for Safety.	System	29 Mar 2021 15:29:21
	(b) (4), (b) (6)	29 Mar 2021 15:28:46
User entered '30303'	Bezuayehu Mandefro	26 Mar 2021 13:02:49
	(b) (4)	



**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 19:19:16
User entered 'US'	System	23 Feb 2021 16:42:14

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	23 Apr 2021 14:43:34
User entered '9'	System	21 Apr 2021 12:56:35
User entered '8'	System	06 Apr 2021 14:49:03
User entered '7'	System	30 Mar 2021 18:47:41
User entered '6'	System	29 Mar 2021 15:29:21
User entered '5'	System	22 Mar 2021 13:28:07
User entered '4'	System	19 Mar 2021 13:03:00
User entered '3'	System	16 Mar 2021 13:25:27
User entered '2'	System	25 Feb 2021 19:19:33
User entered '1'	System	23 Feb 2021 16:42:14

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (7)**

**Generated On: 10 Jun 2021 09:15:35**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:57:25
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
User entered '30/Mar/2021 11:47'	(b) (4) System	30 Mar 2021 18:47:41

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:15:35

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:57:25
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:48:43
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
User entered 'I'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:47:41

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered		
'USA-US120-2021-MRNA-1273-P301000004'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'No (N)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43



**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'No (N)'	System	23 Feb 2021 16:39:43

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 19:19:16
Un-reviewed for Safety.	System	25 Feb 2021 19:18:03
User entered 'Yes (Y)'	System	25 Feb 2021 19:18:03
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'No (N)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Colleen'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Kelley'	System	23 Feb 2021 16:39:43

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:55:46
User closed query 'Please enter address.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 16:55:34
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:48:43
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
Un-reviewed for Safety.	System	29 Mar 2021 15:29:21
User entered empty.	System	29 Mar 2021 15:29:21
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:46
Query 'Please enter address.' answered with 'updated' (Site from CRA).	Bezuayehu Mandefro (b) (4)	26 Mar 2021 13:03:04
User entered '68 Armstrong St'	Bezuayehu Mandefro (b) (4)	26 Mar 2021 13:02:49
User opened query 'Please enter address.' (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 20:05:23

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:56:32
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:48:43
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	29 Mar 2021 15:29:21
Reviewed for Safety.	System	29 Mar 2021 15:29:21
	(b) (4), (b) (6)	29 Mar 2021 15:28:46
User entered 'Atlanta'	Bezuayehu Mandefro	26 Mar 2021 13:02:49
	(b) (4)	



**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'GA'	System	23 Feb 2021 16:39:43

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:57:25
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:48:43
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	29 Mar 2021 15:29:21
Reviewed for Safety.	System	29 Mar 2021 15:29:21
	(b) (4), (b) (6)	29 Mar 2021 15:28:46
User entered '30303'	Bezuayehu Mandefro	26 Mar 2021 13:02:49
	(b) (4)	

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 19:19:16
User entered 'US'	System	23 Feb 2021 16:42:14

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	23 Apr 2021 14:43:34
User entered '9'	System	21 Apr 2021 12:56:35
User entered '8'	System	06 Apr 2021 14:49:03
User entered '7'	System	30 Mar 2021 18:47:41
User entered '6'	System	29 Mar 2021 15:29:21
User entered '5'	System	22 Mar 2021 13:28:07
User entered '4'	System	19 Mar 2021 13:03:00
User entered '3'	System	16 Mar 2021 13:25:27
User entered '2'	System	25 Feb 2021 19:19:33
User entered '1'	System	23 Feb 2021 16:42:14

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (8)**

**Generated On: 10 Jun 2021 09:15:35**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:57:25
User entered '06/Apr/2021 09:48'	System	06 Apr 2021 14:49:03

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:15:35

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 12:56:15
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:58
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:57:25
User entered 'I'	(b) (4), (b) (6)	06 Apr 2021 14:49:03

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered		
'USA-US120-2021-MRNA-1273-P301000004'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43



**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'No (N)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'No (N)'	System	23 Feb 2021 16:39:43

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 19:19:16
Un-reviewed for Safety.	System	25 Feb 2021 19:18:03
User entered 'Yes (Y)'	System	25 Feb 2021 19:18:03
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'No (N)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Colleen'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Kelley'	System	23 Feb 2021 16:39:43



US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:55:46
User closed query 'Please enter address.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 16:55:34
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:48:43
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
Un-reviewed for Safety.	System	29 Mar 2021 15:29:21
User entered empty.	System	29 Mar 2021 15:29:21
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:46
Query 'Please enter address.' answered with 'updated' (Site from CRA).	Bezuayehu Mandefro (b) (4)	26 Mar 2021 13:03:04
User entered '68 Armstrong St'	Bezuayehu Mandefro (b) (4)	26 Mar 2021 13:02:49
User opened query 'Please enter address.' (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 20:05:23

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:56:32
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:48:43
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	29 Mar 2021 15:29:21
Reviewed for Safety.	System	29 Mar 2021 15:29:21
	(b) (4), (b) (6)	29 Mar 2021 15:28:46
User entered 'Atlanta'	Bezuayehu Mandefro	26 Mar 2021 13:02:49
	(b) (4)	

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'GA'	System	23 Feb 2021 16:39:43

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:57:25
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:48:43
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	29 Mar 2021 15:29:21
Reviewed for Safety.	System	29 Mar 2021 15:29:21
	(b) (4), (b) (6)	29 Mar 2021 15:28:46
User entered '30303'	Bezuayehu Mandefro	26 Mar 2021 13:02:49
	(b) (4)	

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 19:19:16
User entered 'US'	System	23 Feb 2021 16:42:14

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	23 Apr 2021 14:43:34
User entered '9'	System	21 Apr 2021 12:56:35
User entered '8'	System	06 Apr 2021 14:49:03
User entered '7'	System	30 Mar 2021 18:47:41
User entered '6'	System	29 Mar 2021 15:29:21
User entered '5'	System	22 Mar 2021 13:28:07
User entered '4'	System	19 Mar 2021 13:03:00
User entered '3'	System	16 Mar 2021 13:25:27
User entered '2'	System	25 Feb 2021 19:19:33
User entered '1'	System	23 Feb 2021 16:42:14

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (9)**

**Generated On: 10 Jun 2021 09:15:35**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:41:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:39:47
User entered '21/Apr/2021 08:56'	System	21 Apr 2021 12:56:35

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 09:15:35

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 14:43:08
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:41:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:39:49
User entered 'I'	(b) (4), (b) (6)	21 Apr 2021 12:56:35



**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered	System	23 Feb 2021 16:39:43
'USA-US120-2021-MRNA-1273-P301000004'		

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'No (N)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Yes (Y)'	System	23 Feb 2021 16:39:43

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'No (N)'	System	23 Feb 2021 16:39:43

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 19:19:16
Un-reviewed for Safety.	System	25 Feb 2021 19:18:03
User entered 'Yes (Y)'	System	25 Feb 2021 19:18:03
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'No (N)'	System	23 Feb 2021 16:39:43



**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Colleen'	System	23 Feb 2021 16:39:43

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'Kelley'	System	23 Feb 2021 16:39:43

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:55:46
User closed query 'Please enter address.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 16:55:34
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:48:43
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
Un-reviewed for Safety.	System	29 Mar 2021 15:29:21
User entered empty.	System	29 Mar 2021 15:29:21
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:46
Query 'Please enter address.' answered with 'updated' (Site from CRA).	Bezuayehu Mandefro (b) (4)	26 Mar 2021 13:03:04
User entered '68 Armstrong St'	Bezuayehu Mandefro (b) (4)	26 Mar 2021 13:02:49
User opened query 'Please enter address.' (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 20:05:23

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:56:32
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:48:43
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	29 Mar 2021 15:29:21
Reviewed for Safety.	System	29 Mar 2021 15:29:21
	(b) (4), (b) (6)	29 Mar 2021 15:28:46
User entered 'Atlanta'	Bezuayehu Mandefro	26 Mar 2021 13:02:49
	(b) (4)	

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 16:42:05
User entered 'GA'	System	23 Feb 2021 16:39:43

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:35

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:57:25
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:48:43
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	29 Mar 2021 15:29:21
Reviewed for Safety.	System	29 Mar 2021 15:29:21
	(b) (4), (b) (6)	29 Mar 2021 15:28:46
User entered '30303'	Bezuayehu Mandefro	26 Mar 2021 13:02:49
	(b) (4)	

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:04:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 19:19:16
User entered 'US'	System	23 Feb 2021 16:42:14

**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:35**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	23 Apr 2021 14:43:34
User entered '9'	System	21 Apr 2021 12:56:35
User entered '8'	System	06 Apr 2021 14:49:03
User entered '7'	System	30 Mar 2021 18:47:41
User entered '6'	System	29 Mar 2021 15:29:21
User entered '5'	System	22 Mar 2021 13:28:07
User entered '4'	System	19 Mar 2021 13:03:00
User entered '3'	System	16 Mar 2021 13:25:27
User entered '2'	System	25 Feb 2021 19:19:33
User entered '1'	System	23 Feb 2021 16:42:14



**US3632075**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (10)**

**Generated On: 10 Jun 2021 09:15:35**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	28 Apr 2021 22:19:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 20:57:44
User entered '23/Apr/2021 10:43'	System	23 Apr 2021 14:43:34

US3632075

Folder: SAE USA-US120-2021-MRNA-1273-P301000004

Form: Safety Report Form (10)

Generated On: 10 Jun 2021 09:15:35

**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.	Colleen Kelley (b) (4)	28 Apr 2021 22:19:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Apr 2021 20:57:47
User entered 'I'	(b) (4), (b) (6)	23 Apr 2021 14:43:34