

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION

**Form Version:** 10-Oct-2020 16:01

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Cohort Selection**

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

1.	Select appropriate response - Protocol version	06 OCT 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** MAIN INFORMED CONSENT

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Oct/20/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

**Form Version:** 15-Sep-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[11201350]
2.	Birth Date:	(b) (6)/1953
3.	Sex:	MALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**eCRF Audit Trail History**

**Date of Visit**

1.	Date of Visit	Oct/20/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 10-Oct-2020 16:00

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**Form Comments**

**Inclusion Criteria Not Met**

1.	Description of Inclusion Criterion Not Met	Not Applicable _____
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**Exclusion Criteria Met**

2.	Description of Exclusion Criterion Met	Not Applicable _____
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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:52

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** DISPOSITION - SCREENING

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation/Death	Oct/20/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hypertension]
	Start Date:	UNK/UNK/1992
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[congestive heart failure]
	Start Date:	UNK/UNK/1992
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[generalized body pain]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[insomnia]
	Start Date:	UNK/UNK/1994
	Ongoing:	YES

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[low testosterone]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[quadruple bypass surgery]
	Start Date:	Dec/UNK/1992
	Ongoing:	NO End Date: Dec/UNK/1992
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[heart attack]
	Start Date:	UNK/UNK/1992
	Ongoing:	NO End Date: UNK/UNK/1992
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[pacemaker difibulator implant]
	Start Date:	UNK/UNK/2010
	Ongoing:	NO End Date: UNK/UNK/2010

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[chronic neck pain]
	Start Date:	UNK/UNK/2009
	Ongoing:	YES
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[chronic back pain]
	Start Date:	UNK/UNK/2007
	Ongoing:	YES

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:57

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** HIV STATUS

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**HIV Status**

1.	Select appropriate response - What is the subject HIV status?	The subject is NOT known to be HIV POSITIVE
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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 10-Oct-2020 16:04

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - BASELINE

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Oct/20/2020
2.	Weight:	[95.1]
3.	Unit:	kg
4.	Height:	[175.0]
5.	Unit:	cm
6.	Body Mass Index:	[31.1]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[36.8]
	Unit:	C
	Temperature Location:	ORAL CAVITY

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** RANDOMIZATION

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Oct/20/2020
2.	Randomization Number:	[271448]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/20/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BMN85J]
5.b	Sample ID	[BMN85K]
5.c	Sample ID	[BP8WH2]

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/20/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP8WH0]
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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** VACCINATION

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**eCRF Audit Trail History**

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/20/2020 16:20
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** REACTOGENICITY DIARY

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/20/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Oct/24/2020
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Oct/24/2020
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:27

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Jan/20/2021
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[98.5]
	Unit:	F
	Temperature Location:	ORAL CAVITY

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/20/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BHVSNC]
5.b	Sample ID	[ ]
5.c	Sample ID	[ ]

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** VACCINATION

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**eCRF Audit Trail History**

**Vaccination**

1.	Was there a temporary delay of vaccination?	YES Date of First Delay: Dec/10/2020  Reason(s) for Temporary Delay of Vaccination FEVER OR ACUTE ILLNESS	
2.	Treatment Name	[BLINDED THERAPY]	
3.	Formulation:	INJECTION	
4.	Dose Date Time:	Jan/20/2021 14:51	<a href="#">Comments</a>
5.	Anatomical Location:	DELTOID MUSCLE	
6.	Body Side:	LEFT	<a href="#">Comments</a>
7.	Route:	INTRAMUSCULAR	
8.	Actual Dose:	[ ]	
9.	Unit:		
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES	<a href="#">Comments</a>

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**eCRF Audit Trail History**

**Date of Visit**

1.	Date of Visit	Feb/24/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

[Form Comments](#)  
[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	Not Done	<a href="#">Comments</a>
2.a	Symptom:	FEVER	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done	<a href="#">Comments</a>
2.b	Symptom:	FATIGUE	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done	<a href="#">Comments</a>
2.c	Symptom:	HEADACHE	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done	<a href="#">Comments</a>
2.d	Symptom:	CHILLS	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done	<a href="#">Comments</a>
2.e	Symptom:	VOMITING	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done	<a href="#">Comments</a>
2.f	Symptom:	DIARRHEA	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done	<a href="#">Comments</a>

090177e196ae3ff\Final\Final On: 01-Apr-2021 05:27 (GMT)



**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	<a href="#">Comments</a>
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	<a href="#">Comments</a>
3.	Injection Site Location:	Not Done _____	<a href="#">Comments</a>
4.	Injection Site Body Side:	Not Done _____	<a href="#">Comments</a>
5.a	Injection Site Reaction:	REDNESS	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Done _____	<a href="#">Comments</a>
5.b	Injection Site Reaction:	SWELLING	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Done _____	<a href="#">Comments</a>
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Done _____	<a href="#">Comments</a>

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Data Complete, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[Form Comments](#)  
[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE	<a href="#">Comments</a>
2.	Sample Type	SERUM	<a href="#">Comments</a>
3.	Sample Collected?	YES Date of Collection: Feb/24/2021	<a href="#">Comments</a>
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]	<a href="#">Comments</a>

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BHVTCV]
5.b	Sample ID	[BJ3D1N]
5.c	Sample ID	[BJ3D1P]

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**Electronic Sample Tracking**

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**Electronic Sample Tracking**

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**Electronic Sample Tracking**

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

**Form:** DATE OF VISIT - ILLNESS ONSET

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	
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090177e196ae3ff\Final\Final On: 01-Apr-2021 05:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

**Form Version:** 20-Feb-2021 02:17

**Form Status:** Not Started

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**Signs and Symptoms**

1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	

**Symptoms**

4.	Symptoms:	
	Was symptom present?	

**Symptoms - Other**

5.	Symptoms - Other Text:	[ ]
----	------------------------	-----

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**Electronic Sample Tracking**

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae3ff\Final\Final On: 01-Apr-2021 05:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**Electronic Sample Tracking**

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 20-Feb-2021 02:19

**Form Status:** Not Started

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**Health Care Utilization**

1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	

**Health Care Utilization Other**

2.	Other Type of Practitioner Specify:	[ ]
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**Health Care Utilization**

3.	Has the subject been hospitalized due to potential COVID-19 illness?	
----	--	--

090177e196ae3ff\Final\Final On: 01-Apr-2021 05:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

**Form:** ILLNESS DETAILS

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Not Started

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**Illness Details**

1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA - New  
Unscheduled Visit

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Not Started

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	
----	-------------------------	--

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA - New  
Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**Electronic Sample Tracking**

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New  
Unscheduled Visit

**Form:** DATE OF VISIT - REPEAT SWAB

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

3.	COVID-19 Repeat Swab:	
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090177e196ae3ff\Final\Final On: 01-Apr-2021 05:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New  
Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**Electronic Sample Tracking**

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	WOUND PUMP DRAINAGE	Dec/7/2020 UNK:UNK	YES	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	PACE MAKER BATTERY CHARGE	Nov/17/2020 UNK:UNK	NO End Date Time:  Nov/17/2020 UNK:UNK	<a href="#">Repeating Pages</a>
3.	ADVERSE EVENT	3	HEMATOMA	Nov/23/2020 UNK:UNK	NO End Date Time:  Nov/23/2020 UNK:UNK	<a href="#">Repeating Pages</a>
4. DELETED	ADVERSE EVENT	4	SUTURE SITE INFECTION	Dec/3/2020 UNK:UNK	YES	<a href="#">Repeating Pages</a>
5.	ADVERSE EVENT	5	Postoperative wound infection to left upper chest	Nov/23/2020 UNK:UNK	YES	<a href="#">Repeating Pages</a>

090177e196ae3ff\Final\Final On: 01-Apr-2021 05:27 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[WOUND PUMP DRAINAGE]
4.	Start Date Time:	Dec/7/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [UNKNOWN]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[PACE MAKER BATTERY CHARGE]
4.	Start Date Time:	Nov/17/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/17/2020 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [HISTORY PACE MAKER]

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

090177e196ae3ff\Final\Final On: 01-Apr-2021 05:27 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[HEMATOMA]
4.	Start Date Time:	Nov/23/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/23/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [UNKNOWN]

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED WITH SEQUELAE
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1120

Subject No: 11201350

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[SUTURE SITE INFECTION]
4.	Start Date Time:	Dec/3/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [UNKNOWN]

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Deleted

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\***

10.	Latest Action Taken with Study Treatment:	<del>NOT APPLICABLE</del>
11.	Was a Concomitant Medication given?	<del>YES</del>
12.	Was a Non-Drug Treatment given?	<del>NO</del>
13.	What was the outcome of this adverse event?:	<del>RECOVERING/RESOLVING</del>
14.	Did the adverse event cause the subject to be discontinued from the study?	<del>NO</del>
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Postoperative wound infection to left upper chest]
4.	Start Date Time:	Nov/23/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES  Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? NO  Did this serious event require or prolong hospitalization? YES  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? NO  Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Pacemaker replacement]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020492747]

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**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Medication Error**

1.	Category:	
2.	Medication Error (Type of Medication Error):	[ ]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

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**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Concomitant Medications**

1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication:  Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	Date:	//

090177e196ae3ff\Final\Final On: 01-Apr-2021 05:27 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Concomitant Medications**

1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication:  Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	Dose:	[ ]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

090177e196ae3ff\Final\Final On: 01-Apr-2021 05:27 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Radiation Treatment**

1.	Category:	
2.	What is the treatment Identifier?	[ ]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[ ]
5.	Start Date:	//
6.	Ongoing?	

090177e196ae3ff\Final\Final On: 01-Apr-2021 05:27 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

#	Transfusion Type	Date of Transfusion	Form Instance
1.			<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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1.	Transfusion Type:	
2.	Date of Transfusion:	//

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Feb/02/2021

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/2/2021
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Feb/02/2021

**Form:** UNPLANNED VISIT

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Unplanned Assessments**

1.	Assessments	CONTACT OUTCOME
----	-------------	-----------------

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Feb/02/2021

**Form:** CONTACT OUTCOME - UNPLANNED

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Feb/2/2021  Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION
3.	Comments:	[ ]

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VITAL SIGNS - TEMP

**Form Version:** 20-Feb-2021 02:16

**Form Status:** Not Started

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**Vital Signs**

1.	Date:	//
----	-------	----

**Vital Signs Details**

2.	Record Identifier:	
	Temperature:	[ ]
	Unit:	
	Temperature Location:	

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Not Started

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**Vaccination**

1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[ ]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**Contact Outcome**

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 6

**Form Version:** 10-Oct-2020 16:01

**Form Status:** Not Started

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**Contact Outcome**

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

**Form Version:** 14-Jan-2021 02:29

**Form Status:** Not Started

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**Informed Consent - Asymptomatic Surveillance**

1.	Consent Was:	
----	--------------	--

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**Electronic Sample Tracking**

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
----	-----------	-----

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**Electronic Sample Tracking**

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
----	-----------	-----

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[Form Comments](#)  
[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation/Death :	Feb/24/2021	<a href="#">Comments</a>
2.	Phase of Disposition:	VACCINATION	<a href="#">Comments</a>
3.	Status:	COMPLETED	<a href="#">Comments</a>
4.	Specify Status:	[ ]	<a href="#">Comments</a>

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/12/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** FURTHER VACCINATION CONFIRMATION

**Form Version:** 10-Dec-2020 02:25

**Form Status:** Data Complete, Frozen

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2
----	---	--

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**Disposition - Follow-Up**

1.	Date of Completion/Discontinuation/Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** TREATMENT UNBLINDED

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Jan/12/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION



**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[Form Comments](#)  
[eCRF Audit Trail History](#)

**Withdrawal Of Consent**

			<a href="#">Comments</a>
1.	Withdrawal of Consent Date :	Not Done <hr/> //	

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** DEATH DETAILS CODED

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[Form Comments](#)  
[eCRF Audit Trail History](#)

**Death Details**

1.	Date of Collection / Notification of Death:	Not Done _____ //	<a href="#">Comments</a>
----	---	-------------------------	--------------------------

**Cause of Death**

2.	Cause of Death Status:	Not Done _____
	Cause of Death:	Not Done _____ [ ]

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Feb/24/2021

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Not Started

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**Casebook Signature Form**

1.	Casebook Signature	
----	--------------------	--

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Not Started

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[Audit Trail](#)

This form requires signing by a member of each of the following signature groups:

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
------	-------------------	------	------	--------

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 10-Oct-2020 16:00

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
Form	Oct-21-2020 08:12:28 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** VACCINATION - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
4	Jan-22-2021 09:07:14 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	
4	Jan-11-2021 15:45:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** VACCINATION - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
6	Mar-04-2021 09:07:25 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	
6	Jan-11-2021 15:45:34 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** VACCINATION - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
11	Mar-04-2021 09:07:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	
11	Jan-11-2021 15:45:47 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - Comments

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
Form	Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
1	Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - Comments

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
2.a	Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
2.b	Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - Comments

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
2.c	Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
2.d	Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - Comments

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[Back to Form](#)

Item	Date	User	Comment
2.e	Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done



**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - Comments

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[Back to Form](#)

Item	Date	User	Comment
2 f	Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - Comments

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[Back to Form](#)

Item	Date	User	Comment
2.g	Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - Comments

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[Back to Form](#)

Item	Date	User	Comment
2 h	Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - Comments

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[Back to Form](#)

Item	Date	User	Comment
3	Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - Comments

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
4	Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - Comments

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
5.a	Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - Comments

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
5.b	Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - Comments

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
5.c	Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done



**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
Form	Mar-11-2021 14:42:18 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	
Form	Jan-11-2021 15:49:46 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[Back to Form](#)

Item	Date	User	Comment
1	Mar-11-2021 14:42:18 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	
1	Jan-11-2021 15:49:46 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[Back to Form](#)

Item	Date	User	Comment
2	Mar-11-2021 14:42:18 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	
2	Jan-11-2021 15:49:46 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[Back to Form](#)

Item	Date	User	Comment
3	Mar-11-2021 14:42:18 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	
3	Jan-11-2021 15:49:46 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

**Form Version:** 22-Apr-2020 21:03

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**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[Back to Form](#)

Item	Date	User	Comment
4	Mar-11-2021 14:42:18 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	
4	Jan-11-2021 15:49:46 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT - Comments

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-12-2021 09:01:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	
Form	Jan-27-2021 09:15:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** End of Treatment

**Form Version:** 10-Dec-2020 02:29

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** DISPOSITION - TREATMENT - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
1	Mar-12-2021 09:01:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	
1	Jan-27-2021 09:15:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** End of Treatment

**Form Version:** 10-Dec-2020 02:29

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** DISPOSITION - TREATMENT - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[Back to Form](#)

Item	Date	User	Comment
2	Mar-12-2021 09:01:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	
2	Jan-27-2021 09:15:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable



**Header Text:** c4591001

**Visit:** End of Treatment

**Form Version:** 10-Dec-2020 02:29

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** DISPOSITION - TREATMENT - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
3	Mar-12-2021 09:01:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	
3	Jan-27-2021 09:15:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** End of Treatment

**Form Version:** 10-Dec-2020 02:29

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** DISPOSITION - TREATMENT - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
4	Mar-12-2021 09:01:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	
4	Jan-27-2021 09:15:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** WITHDRAWAL OF CONSENT - Comments

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
Form	Feb-26-2021 11:36:46 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** Disposition

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** WITHDRAWAL OF CONSENT - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
1	Feb-26-2021 11:36:46 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** DEATH DETAILS CODED - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
Form	Feb-26-2021 11:36:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

**Header Text:** c4591001

**Visit:** Disposition

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** DEATH DETAILS CODED - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
1	Feb-26-2021 11:36:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Not Started

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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This form requires signing by a member of each of the following signature groups:

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
------	-------------------	------	------	--------

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 10-Oct-2020 16:01

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** COHORT\_SELECTION - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Oct-21-2020 08:10:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 06 OCT 2020	Initial Entry

*2. Select appropriate response - What cohort does the subject belong to?*

Date	Location	User	Value	Reason
Oct-21-2020 08:10:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> STAGE 3 COHORTS	Initial Entry



**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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*I. Consent Was:*

Date	Location	User	Value	Reason
Oct-21-2020 08:11:09 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Oct/20/2020	Initial Entry

Header Text: c4591001

Visit: COHORT\_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Subject ID**

Date	Location	User	Value	Reason
Oct-21-2020 08:10:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11201350	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Oct-21-2020 08:10:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1953	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Oct-21-2020 08:11:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Oct-21-2020 08:11:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HISPANIC OR LATINO(A) OR O F SPANISH ORIGIN	Initial Entry

**5. Race: (Check X all that apply):**

Date	Location	User	Value	Reason
Oct-21-2020 08:11:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae3ff\Final\Final On: 01-Apr-2021 05:27 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-21-2020 08:12:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/20/2020	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:52

Site No: 1120

Subject No: 11201350

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Oct-21-2020 08:12:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/20/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-21-2020 08:12:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-21-2020 08:12:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1120

Subject No: 11201350

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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*1.a*

Date	Location	User	Value	Reason
Oct-21-2020 08:14:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number</b> 1 : <b>Medical History T</b> hypertension <b>erm:</b> <b>Start Date:</b> UNK/UNK/1 992 <b>Ongoing:</b> YES	Initial Entry

*1.a Line/MH Number:*

Date	Location	User	Value	Reason
Oct-21-2020 08:14:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

*1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:*

Date	Location	User	Value	Reason
Dec-17-2020 10:09:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Dec-17-2020 10:01:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	UPDATED
Dec-16-2020 10:42:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Clinical_ AER#2020492747_Suture site infection (Pace maker removal_was reported as serious in Safety database but not recorded on AE log of CRF. Please confirm and update CRF. Thank you.
Oct-21-2020 08:14:32 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> hypertension	Initial Entry

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1120

Subject No: 11201350

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

Time (US & Canada)

**1.a Start Date:**

Date	Location	User	Value	Reason
Oct-21-2020 08:14:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1992	Initial Entry

**1.a Ongoing:**

Date	Location	User	Value	Reason
Oct-21-2020 08:14:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.b**

Date	Location	User	Value	Reason
Oct-21-2020 08:14:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 2 <b>Medical History Term:</b> congestive heart failure <b>Start Date:</b> UNK/UNK/1992 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1120

Subject No: 11201350

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

***1.b Line/MH Number:***

Date	Location	User	Value	Reason
Oct-21-2020 08:14:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

***1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Oct-21-2020 08:14:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> congestive heart failure	Initial Entry

***1.b Start Date:***

Date	Location	User	Value	Reason
Oct-21-2020 08:14:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1992	Initial Entry

***1.b Ongoing:***

Date	Location	User	Value	Reason
Oct-21-2020 08:14:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.c***

Date	Location	User	Value	Reason
Oct-21-2020 08:15:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 3 <b>Medical History Term:</b> generalized body pain <b>Start Date:</b> UNK/UNK/2010 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1120

Subject No: 11201350

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

**I.c Line/MH Number:**

Date	Location	User	Value	Reason
Oct-21-2020 08:15:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 3	Initial Entry

**I.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Oct-21-2020 08:15:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> generalized body pain	Initial Entry

**I.c Start Date:**

Date	Location	User	Value	Reason
Oct-21-2020 08:15:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/2010	Initial Entry

**I.c Ongoing:**

Date	Location	User	Value	Reason
Oct-21-2020 08:15:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

**I.d**

Date	Location	User	Value	Reason
Oct-21-2020 08:15:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> <b>Line/MH Number 4</b> : <b>Medical History T insomnia</b> <b>erm:</b> <b>Start Date:</b> UNK/UNK/1 994 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1120

Subject No: 11201350

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

***1.d Line/MH Number:***

Date	Location	User	Value	Reason
Oct-21-2020 08:15:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

***1.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Oct-21-2020 08:15:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> insomnia	Initial Entry

***1.d Start Date:***

Date	Location	User	Value	Reason
Oct-21-2020 08:15:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1994	Initial Entry

***1.d Ongoing:***

Date	Location	User	Value	Reason
Oct-21-2020 08:15:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.e***

Date	Location	User	Value	Reason
Oct-21-2020 08:16:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number</b> 5 : <b>Medical History T</b> low testosterone: ne <b>Start Date:</b> UNK/UNK/2010 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1120

Subject No: 11201350

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

***I.e Line/MH Number:***

Date	Location	User	Value	Reason
Oct-21-2020 08:16:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

***I.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Oct-21-2020 08:16:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> low testosterone	Initial Entry

***I.e Start Date:***

Date	Location	User	Value	Reason
Oct-21-2020 08:16:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2010	Initial Entry

***I.e Ongoing:***

Date	Location	User	Value	Reason
Oct-21-2020 08:16:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***I.f***

Date	Location	User	Value	Reason
Oct-21-2020 08:27:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 6 <b>Medical History Term:</b> quadruple bypass surgery <b>Start Date:</b> Dec/UNK/1992 <b>Ongoing:</b> NO End Date: Dec/UNK/1992	Initial Entry

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1120

Subject No: 11201350

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

***1.f Line/MH Number:***

Date	Location	User	Value	Reason
Oct-21-2020 08:27:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

***1.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Oct-21-2020 08:27:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> quadruple bypass surgery	Initial Entry

***1.f Start Date:***

Date	Location	User	Value	Reason
Oct-21-2020 08:27:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/UNK/1992	Initial Entry

***1.f Ongoing:***

Date	Location	User	Value	Reason
Oct-21-2020 08:27:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  Dec/UNK/1992	Initial Entry

***1.g***

Date	Location	User	Value	Reason
Oct-21-2020 08:27:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 7 <b>Medical History</b> heart attack <b>Term:</b> <b>Start Date:</b> UNK/UNK/1992	Initial Entry

090177e196ae3ff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1120

Subject No: 11201350

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

			Ongoing:	NO End Date:  UNK/UNK/ 1992	
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**I.g Line/MH Number:**

Date	Location	User	Value	Reason
Oct-21-2020 08:27:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 7	Initial Entry

**I.g Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Oct-21-2020 08:27:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> heart attack	Initial Entry

**I.g Start Date:**

Date	Location	User	Value	Reason
Oct-21-2020 08:27:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/1992	Initial Entry

**I.g Ongoing:**

Date	Location	User	Value	Reason
Oct-21-2020 08:27:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date:  UNK/UNK/1992	Initial Entry

**I.h**

Date	Location	User	Value	Reason
Oct-21-2020 08:28:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Nu 8 mber:	Initial Entry

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1120

Subject No: 11201350

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

			<b>Medical History Term:</b> pacemaker difibulator implant <b>Start Date:</b> UNK/UNK/2010 <b>Ongoing:</b> NO End Date: UNK/UNK/2010	
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**1.h Line/MH Number:**

Date	Location	User	Value	Reason
Oct-21-2020 08:28:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 8	Initial Entry

**1.h Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Oct-21-2020 08:28:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> pacemaker difibulator implant	Initial Entry

**1.h Start Date:**

Date	Location	User	Value	Reason
Oct-21-2020 08:28:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2010	Initial Entry

**1.h Ongoing:**

Date	Location	User	Value	Reason
Oct-21-2020 08:28:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: UNK/UNK/2010	Initial Entry

**1.i**

Date	Location	User	Value	Reason
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090177e196ae3ff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1120

Subject No: 11201350

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

Oct-21-2020 08:28:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number</b> 9 : <b>Medical History T</b> chronic neck <b>erm:</b> pain <b>Start Date:</b> UNK/UNK/2 009 <b>Ongoing:</b> YES	Initial Entry
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*1.i Line/MH Number:*

Date	Location	User	Value	Reason
Oct-21-2020 08:28:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 9	Initial Entry

*1.i Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:*

Date	Location	User	Value	Reason
Oct-21-2020 08:28:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> chronic neck pain	Initial Entry

*1.i Start Date:*

Date	Location	User	Value	Reason
Oct-21-2020 08:28:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2009	Initial Entry

*1.i Ongoing:*

Date	Location	User	Value	Reason
Oct-21-2020 08:28:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

*1.j*

Date	Location	User	Value	Reason
Oct-21-2020 08:28:49 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number</b> 10	Initial Entry

090177e196ae3ff\Final\Final On: 01-Apr-2021 05:27 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

Time (US & Canada)

:

**Medical History Term:** chronic back pain

**Start Date:** UNK/UNK/2007

**Ongoing:** YES

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1120

Subject No: 11201350

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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***1.j Line/MH Number:***

Date	Location	User	Value	Reason
Oct-21-2020 08:28:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10	Initial Entry

***1.j Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Oct-21-2020 08:28:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> chronic back pain	Initial Entry

***1.j Start Date:***

Date	Location	User	Value	Reason
Oct-21-2020 08:28:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2007	Initial Entry

***1.j Ongoing:***

Date	Location	User	Value	Reason
Oct-21-2020 08:28:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:57

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** HIV STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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*1. Select appropriate response - What is the subject HIV status?*

Date	Location	User	Value	Reason
Oct-21-2020 08:29:03 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> The subject is NOT known to be H IV POSITIVE	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 10-Oct-2020 16:04

Site No: 1120

Subject No: 11201350

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Date:**

Date	Location	User	Value	Reason
Oct-21-2020 08:31:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/20/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Oct-21-2020 08:31:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 95.1	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Oct-21-2020 08:31:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Oct-21-2020 08:31:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 175.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Oct-21-2020 08:31:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Oct-21-2020 08:31:13 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 31.1	Initial Entry

090177e196ae3ff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 10-Oct-2020 16:04

Site No: 1120

Subject No: 11201350

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

Time (US & Canada)

7.a

Date	Location	User	Value	Reason
Oct-21-2020 08:31:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 36.8 <b>Temperature Unit:</b> C <b>Temperature Locat</b> ORAL CAVI <b>ion::</b> TY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Oct-21-2020 08:31:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Oct-21-2020 08:31:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.8	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Oct-21-2020 08:31:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Oct-21-2020 08:31:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** RANDOMIZATION - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Oct-21-2020 08:33:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/20/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Oct-21-2020 08:33:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 271448	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-21-2020 08:33:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-21-2020 08:33:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-21-2020 15:11:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-21-2020 08:33:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-21-2020 08:33:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> YES Date of Collection:  Oct/20/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-21-2020 15:11:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Sample ID: BMN85J	Initial Entry

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

5.a Sample ID

Date	Location	User	Value	Reason
Oct-21-2020 15:11:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BMN85J	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-21-2020 15:11:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BMN85K	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-21-2020 15:11:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BMN85K	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-21-2020 15:12:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP8WH2	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-21-2020 15:12:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP8WH2	Initial Entry

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-21-2020 08:33:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-21-2020 08:33:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-21-2020 15:11:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-21-2020 08:33:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-21-2020 08:33:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> YES Date of Collection:  Oct/20/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-21-2020 15:11:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Sample ID: BP8WH0	Initial Entry

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-21-2020 15:11:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP8WH0	Initial Entry



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1120

Subject No: 11201350

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Oct-21-2020 08:34:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Oct-21-2020 08:34:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Oct-21-2020 08:34:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Oct-21-2020 08:34:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/20/2020 16:20	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Oct-21-2020 08:34:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Oct-21-2020 08:34:26 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae3ff\Final\Final On: 01-Apr-2021 05:27 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

Time (US & Canada)	(b) (4), (b) (6)
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**7. Route:**

Date	Location	User	Value	Reason
Oct-21-2020 08:34:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Oct-21-2020 08:34:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

**11. Was the subject observed for at least the protocol specified observation period after investigational product administration?**

Date	Location	User	Value	Reason
Oct-21-2020 08:34:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Oct-21-2020 08:34:35 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES - REACTOGENICITY E-DI ARY COLLECTED FOR THIS S UBJECT	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:02

Site No: 1120

Subject No: 11201350

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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*I. Date of Visit*

Date	Location	User	Value	Reason
Mar-08-2021 08:17:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Deleted	Changed Information
Mar-08-2021 08:17:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : Jan/20/2021	Changed Information
Mar-04-2021 17:27:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Candidate	DM: Do not issue query; do not freeze forms. Per query response on Nasal Swab, site needs to update all visit forms. Query can be closed after updates are made.
Dec-31-2020 03:34:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-30-2020 10:20:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : Nov/9/2020	New Information
Dec-30-2020 10:20:36 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answer	SUBJECT CAME IN FOR VAX2 VACCINATION

090177e196ae3ff\Final\Final On: 01-Apr-2021 05:27 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

Eastern Time (US & Canada)			d	UPDATED
Dec-30-2020 07:13:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	DM 2: Thanks for the response, however the SWAB PFE, VACIN TRT forms are yet to be updated, kindly review and update, else clarify.
Dec-22-2020 01:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Candidate	DM: Please review VACIN TRT form once entered. Thanks.
Dec-21-2020 09:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Subject has not came in for vax
Dec-21-2020 04:10:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed per SITE response, added to PD tracker for Clinical Review
Dec-21-2020 01:46:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	DM1: Please complete VACIN TRT form.
Dec-18-2020 09:16:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	updated

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:02

Site No: 1120

Subject No: 11201350

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

Dec-18-2020 08:56:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	THIS IS CORRECT
Dec-18-2020 05:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: Kindly consider to update missing SWAB PFE, VACIN TRT forms or else clarify. Thank you.
Dec-18-2020 03:37:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	PDQ: Date of visit at V2_VAX2_L is out of window for 28 days from V1_DAY1_VAX1_L Dose Date. Please verify and update. Else, confirm in query response appropriately. (b) (4)
Dec-17-2020 09:58:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : Dec/10/2020	Initial Entry

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Mar-10-2021 19:50:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Issue resolved
Mar-04-2021 17:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	DM: Do not issue query; do not freeze forms. Per query response on Nasal Swab, site needs to update all visit forms. Query can be closed after updates are made.
Dec-17-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Dec-17-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> N O	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Dec-17-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

**2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Date	Location	User	Value	Reason
Dec-17-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Jan-15-2021 10:52:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: FATIGUE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: YES Ongoing? NO Stop Date: Oct /24/ 2020	Changed Information
Dec-18-2020 08:57:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: FATIGUE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: YES Ongoing? ?	Transcription Error
Dec-17-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: FATIGUE	Initial Entry

090177e196ae3ff\Final\Final On: 01-Apr-2021 05:27 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

			<b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	
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Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

2.b Symptom:

Date	Location	User	Value	Reason
Dec-17-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-15-2021 10:52:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES Ongoing?  NO  Stop Date:  Oct/24/2020	Changed Information
Jan-11-2021 08:41:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Per response
Jan-08-2021 10:26:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	yes subject has not received vax 2
Jan-08-2021 04:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	eDiary: Please confirm if Fatigue associated with Vaccination 1 (20Oct20) is still ongoing. Else, Please review and update stop date as appropriate. Thanks
Dec-22-2020 07:45:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Data updated by site.
Dec-18-2020 08:57:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Dec-18-2020 08:57:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Ongoing?  YES	Transcription Error
Dec-18-2020 02:02:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	eDiary: Per diary records, FATIGUE present on Last day however inform entered with 'No' for the same. Please verify and update. If diary entered in error, please enter stop date as last date of diary. Thanks.
Dec-17-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Dec-17-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b>  HE AD AC HE  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

2.c Symptom:

Date	Location	User	Value	Reason
Dec-17-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Dec-17-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Dec-17-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: CH IL LS Were fever or systemic sym NO ptoms present on the last da y the Subject Diary was co mpleted?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Dec-17-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Dec-17-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.e

090177e196ae3ff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Date	Location	User	Value	Reason
Dec-17-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> VO MIT ING  <b>Were fever or systemic sy mptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

*2.e Symptom:*

Date	Location	User	Value	Reason
Dec-17-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

*2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?*

Date	Location	User	Value	Reason
Dec-17-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*2.f*

Date	Location	User	Value	Reason
Jan-15-2021 10:52:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DIARRH EA	Changed Information

090177e196ae3ff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

			<p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?: YES Ongoing? NO</p> <p>Stop Date: Oct /24/ 2020</p>	
Dec-18-2020 08:57:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p><b>Symptom::</b> DIAR RHEA</p> <p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?: YES Ongoing? ?</p> <p>YES</p>	Transcription Error
Dec-17-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p><b>Symptom::</b> DIARRHEA</p> <p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO</p>	Initial Entry

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

2.f Symptom:

Date	Location	User	Value	Reason
Dec-17-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-18-2021 02:33:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Data updated by site.
Jan-15-2021 10:52:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Jan-15-2021 10:52:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES Ongoing?  NO  Stop Date:  Oct/24/2020	Changed Information
Jan-11-2021 08:40:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	eDiary RQ1: Thanks for the detailed response. Please update stop date for Diarrhea once available and then respond to the query. Thanks.
Jan-08-2021 14:12:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	waiting on medical records to see when diarrhea stopped
Jan-08-2021 04:20:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	eDiary: Please confirm if Diarrhea associated with Vaccination 1 (20Oct20) is still

090177e196ae3ff\Final\Final On: 01-Apr-2021 05:27 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

				ongoing. Else, Please review and update stop date as appropriate. Thanks
Dec-22-2020 07:45:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Data updated by site.
Dec-18-2020 08:57:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-18-2020 08:57:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Ongoing?  YES	Transcription Error
Dec-18-2020 02:03:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	eDiary: Per diary records, DIARRHEA present on Last day however inform entered with 'No' for the same. Please verify and update. If diary entered in error, please enter stop date as last date of diary. Thanks.
Dec-17-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.g**

Date	Location	User	Value	Reason
Dec-17-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE ED MUS CLE PAI N	Initial Entry



Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
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2.g Symptom:

Date	Location	User	Value	Reason
Dec-17-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENER MUSCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Dec-17-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Dec-17-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSENER JOINT PAIN  Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae3ff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

**2.h Symptom:**

Date	Location	User	Value	Reason
Dec-17-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR WORSENERD JOINT PA IN	Initial Entry

**2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Dec-17-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**3. Injection Site Location:**

Date	Location	User	Value	Reason
Dec-17-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

**4. Injection Site Body Side:**

Date	Location	User	Value	Reason
Dec-17-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> LEFT	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-17-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <b>Injection Site Reaction::</b> RE DN ESS  <b>Were injection site reaction NO s present on the last day th e Subject Diary was comple ted?:</b>	Initial Entry

**5.a Injection Site Reaction:**

090177e196ae3ff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Date	Location	User	Value	Reason
Dec-17-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> REDNESS	Initial Entry

**5.a Were injection site reactions present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Dec-17-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Dec-17-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction:: SWE LLI NG Were injection site reactio ns present on the last day t he Subject Diary was com pleted?: NO	Initial Entry

**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Dec-17-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> SWELLING	Initial Entry

**5.b Were injection site reactions present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Dec-17-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
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090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Dec-17-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> PAIN AT INJECTION SITE <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry
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**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Dec-17-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

**5.c Were injection site reactions present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Dec-17-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 10-Dec-2020 02:27

Site No: 1120

Subject No: 11201350

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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**I. Date:**

Date	Location	User	Value	Reason
Mar-08-2021 08:18:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Deleted	Changed Information
Mar-08-2021 08:18:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/20/2021	Changed Information
Mar-04-2021 17:28:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Candidate	DM: Do not issue query; do not freeze forms. Per query response on Nasal Swab, site needs to update all visit forms. Query can be closed after updates are made.
Feb-01-2021 00:48:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-29-2021 14:29:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Subject had a delay of Vax.
Jan-25-2021 02:53:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM: Page has been unfrozen. Please update.
Jan-22-2021 09:09:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Please unfreeze all other pages
Jan-22-2021 09:07:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Vital Signs Date is not same as Vaccination Date in the same visit. Please review and update as appropriate or clarify.

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Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 10-Dec-2020 02:27

Site No: 1120

Subject No: 11201350

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

Dec-30-2020 10:21:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-30-2020 10:21:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/9/2020	Transcription Error
Dec-30-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Vital Signs Date is not same as Vaccination Date in the same visit. Please review and update as appropriate or clarify.
Dec-17-2020 09:59:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/10/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Mar-08-2021 08:18:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier</b> 1 :: <b>Temperature:</b> 98.5 <b>Temperature Uni</b> F <b>t:</b> <b>Temperature Loc</b> ORAL CAV <b>ation::</b> ITY	Changed Information
Dec-17-2020 09:59:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier</b> 1 :: <b>Temperature:</b> 98.4 <b>Temperature Uni</b> F <b>t:</b> <b>Temperature Loc</b> ORAL CAV <b>ation::</b> ITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
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090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 10-Dec-2020 02:27

Site No: 1120

Subject No: 11201350

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

Dec-17-2020 09:59:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry
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**2.a Temperature:**

Date	Location	User	Value	Reason
Mar-08-2021 08:18:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 98.5	Changed Information
Dec-17-2020 09:59:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 98.4	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Dec-17-2020 09:59:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> F	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Dec-17-2020 09:59:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> ORAL CAVITY	Initial Entry

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Dec-18-2020 09:12:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-18-2020 09:12:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-08-2021 10:01:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rivkah Rosen (b) (4)	Query 6: Closed	Response satisfies query
Mar-08-2021 08:17:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Answered	Answer Auto Query
Mar-04-2021 17:26:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Reissued:Opened	DM: All visit forms have been unfrozen. Please update as needed.
Mar-04-2021 08:59:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Answered	Reaching out to CRA to have unfrozen.
Mar-01-2021 15:41:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Reissued:Opened	DM: Unfrozen. Please update data per query response provided. Thank you.
Feb-26-2021 15:29:49 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Answered	I NEED THE WHOLE VISIT

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)



Header Text: c4591001

Visit: V2\_VAX2\_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Time (US & Canada)				UNFROZEN
Feb-24-2021 06:42:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Reissued:Opened	DM: Please update data per query response provided. Thank you.
Feb-23-2021 16:12:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Answered	PLEASE UNFREEZE DATE OF VISIT
Feb-23-2021 16:12:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 7: Deleted	Close Auto Query
Feb-23-2021 16:11:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 7: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-23-2021 16:11:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Opened	Date of Collection 20/Jan/2021 is greater than Date of Visit 09/Nov/2020. Please review and update as appropriate, else clarify.
Feb-23-2021 16:11:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/20/2021	New Information
Dec-18-2020 09:15:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Closed	Close Auto Query
Dec-18-2020 09:15:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please

090177e196ae3ff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

				provide reason' is missing. Please review and update as appropriate.
Dec-18-2020 09:15:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Deleted	Close Auto Query
Dec-18-2020 09:15:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Transcription Error
Dec-18-2020 09:15:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-18-2020 09:15:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Dec-18-2020 09:14:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	There are more than 1 barcode present for sample collection. Please review and correct as appropriate.
Dec-18-2020 09:14:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Dec-18-2020 09:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	There are more than 1 barcode present for sample collection. Please review and correct as appropriate.
Dec-18-2020 09:12:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-18-2020 09:12:10 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no

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Header Text: c4591001

Visit: V2\_VAX2\_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Time (US & Canada)				barcodes are entered. Please review and correct as appropriate.
Dec-18-2020 09:12:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Dec/10/2020	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Feb-23-2021 16:11:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	New Information
Dec-21-2020 01:51:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed as not found in today's INVALID CHAR report
Dec-18-2020 09:16:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	updated
Dec-18-2020 09:15:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Entered text has either a carriage return (line break) or extra spaces at the end of the text or between words. Please correct by removing all data in the field and re-enter without adding extra spaces or using enter or tab keys.
Dec-18-2020 09:15:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> No nasal swab collected at this visit	Initial Entry

**5.a**

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Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

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Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Feb-23-2021 16:12:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BHVSNC	Initial Entry
Dec-18-2020 09:14:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b>	Transcription Error
Dec-18-2020 09:12:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BMN8HN	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-23-2021 16:12:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BHVSNC	Initial Entry
Dec-18-2020 09:14:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-18-2020 09:12:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BMN8HN	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-18-2020 09:15:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b>	Transcription Error
Dec-18-2020 09:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BMN8HP	Initial Entry

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Header Text: c4591001

Visit: V2\_VAX2\_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

5.b Sample ID

Date	Location	User	Value	Reason
Dec-18-2020 09:15:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-18-2020 09:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BMN8HP	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-18-2020 09:15:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b>	Transcription Error
Dec-18-2020 09:12:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR5R08	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-18-2020 09:15:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-18-2020 09:12:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR5R08	Initial Entry

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Header Text: c4591001

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Form Version: 10-Dec-2020 02:26

Site No: 1120

Subject No: 11201350

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Mar-10-2021 19:44:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Issue resolved
Mar-04-2021 17:28:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	DM: Do not issue query; do not freeze forms. Per query response on Nasal Swab, site needs to update all visit forms. Query can be closed after updates are made.
Dec-18-2020 09:14:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of First Delay:  Dec/10/2020  Reason(s) for Temporary Delay of Vaccination  FEVER OR ACUTE ILLNESS	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jan-22-2021 09:07:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry
Jan-08-2021 10:33:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Dec-30-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

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Header Text: c4591001

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Site No: 1120

Subject No: 11201350

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

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3. Formulation:

Date	Location	User	Value	Reason
Jan-22-2021 09:07:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry
Jan-08-2021 10:33:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Dec-30-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jan-31-2021 23:43:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Jan-29-2021 14:29:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Subject had a delay of vax.
Jan-25-2021 12:48:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	DM: Please update data per query response provided. Thank you.
Jan-22-2021 09:08:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	all forms are frozen.
Jan-22-2021 09:07:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Dose Date is not equal to Date of Visit 09/Nov/2020 of the corresponding Visit. Please review and update as appropriate.
Jan-22-2021 09:07:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Answer Auto Query

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Header Text: c4591001

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Site No: 1120

Subject No: 11201350

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

Jan-22-2021 09:07:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Jan/20/2021 14:51	Initial Entry
Jan-22-2021 09:07:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b>	Initial Entry
Jan-14-2021 23:55:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Reissued:Candidate	Please review this query once data is entered on Vaccination CRF.
Jan-13-2021 10:44:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	waiting for CRA to move forward with subject
Jan-12-2021 05:16:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Reissued:Opened	Thank you. Please provide date at which missing information will be available for data entry.
Jan-11-2021 15:46:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	UPDATED TO NOT APPLICABLE UNTIL SUBEJCT GETS VAXED
Jan-11-2021 15:45:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Not Applicable	Initial Entry
Jan-11-2021 03:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Reissued:Opened	DM1: Kindly review and provide details on this form as appropriate to avoid yellow traffic light. Else clarify.
Jan-08-2021 10:33:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Answer Auto Query
Jan-08-2021 10:33:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b>	Transcription Error

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Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 10-Dec-2020 02:26

Site No: 1120

Subject No: 11201350

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

Dec-31-2020 05:38:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Data is not updated per query. Dose Date Time (9/Nov/2020) is before Date of First delay (10/Dec/2020). Kindly verify both the dates and update CRF as needed. Else clarify in query response.
Dec-30-2020 10:21:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	TEMP DELAY UPDATED
Dec-30-2020 10:20:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Dec-30-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Dose Date is not equal to Date of Visit 10/Dec/2020 of the corresponding Visit. Please review and update as appropriate.
Dec-30-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	"Dose Date" is before "Date of First delay" 10/Dec/2020. Please review and update as appropriate.
Dec-30-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/9/2020 14:14	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-22-2021 09:07:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry
Jan-08-2021 10:33:42	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Transcription Error

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Header Text: c4591001

Visit: V2\_VAX2\_L

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Site No: 1120

Subject No: 11201350

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

(UTC-05:00) Eastern Time (US & Canada)		(autocalc)		
Dec-30-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Mar-04-2021 09:07:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry
Mar-04-2021 09:07:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Jan-11-2021 15:45:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Jan-08-2021 10:34:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-30-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Jan-22-2021 09:07:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry
Jan-08-2021 10:33:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Dec-30-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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Site No: 1120

Subject No: 11201350

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

Date	Location	User	Value	Reason
Jan-22-2021 09:07:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry
Jan-08-2021 10:33:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Dec-30-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

**II. Was the subject observed for at least the protocol specified observation period after investigational product administration?**

Date	Location	User	Value	Reason
Mar-04-2021 09:07:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry
Mar-04-2021 09:07:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Jan-11-2021 15:45:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Jan-08-2021 10:34:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-30-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form Version: 22-Apr-2020 21:02

Site No: 1120

Subject No: 11201350

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

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*I. Date of Visit*

Date	Location	User	Value	Reason
Mar-12-2021 10:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 4: Closed	Response satisfies query
Mar-12-2021 09:01:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	updated
Mar-12-2021 09:00:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Deleted	Close Auto Query
Mar-11-2021 16:09:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 4: Reissued:Opened	CLINQUERY: Visit updated with new data. Please remove the 'erroneous' entry on this page. Please also update the EOT page to reflect end of treatment phase now that V3 is complete
Mar-11-2021 14:42:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Candidate	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level.
Mar-11-2021 14:42:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	New Information

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Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Mar-11-2021 14:42:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Feb/24/2021	New Information
Mar-09-2021 08:33:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 4: Opened	CLINQUERY: Vax 2 was administered 20Jan21. Please review and confirm if V3 has been completed (month post V2). Page unfreeze can be actioned for data entry, if so.
Jan-12-2021 01:15:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 3: Closed	Closed as data updated.
Jan-11-2021 15:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 3: Answered	UPDATED
Jan-11-2021 01:23:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Closed	Closing as visit is marked Erroneous
Jan-11-2021 01:07:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 3: Opened	DM: Erroneous visit is marked. However, data is present on SYMPRDATE form. Kindly consider to erase the data from SYMPRDATE form and add form level comment by selecting Not Done or Not Applicable option on SYMPRDATE form accordingly else, clarify.
Jan-08-2021 10:35:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	visit entered in error

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Jan-08-2021 10:34:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Jan-05-2021 01:39:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-04-2021 08:54:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	UPDATED
Dec-31-2020 04:38:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: If V3 is performed please update EOT. Thank you.
Dec-31-2020 04:36:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly consider to update missing SAMP TRK form or else clarify. Thank you.
Dec-30-2020 10:22:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/7/2020	Initial Entry

**2. Erroneous Visit**

Date	Location	User	Value	Reason
Mar-12-2021 09:00:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Jan-08-2021 10:34:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ERRONEOUS VISIT	Initial Entry

090177e196ae3ff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

[Back to Form](#)

**I. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Jan-08-2021 10:34:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-30-2020 10:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R  Were fever or systemic sym ptoms present on the last d ay the Subject Diary was c ompleted?: Not Do ne	Initial Entry
Jan-11-2021 15:49:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R  Were fever or systemic sym ptoms present on the last da y the Subject Diary was co mpleted?:	Transcription Error
Dec-30-2020 10:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R	Initial Entry

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
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2.a Symptom:

Date	Location	User	Value	Reason
Dec-30-2020 10:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry
Jan-11-2021 15:49:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Dec-30-2020 10:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> FA TIG UE  Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry
Jan-11-2021 15:49:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> FA TIG UE	Transcription Error

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)



Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
Dec-30-2020 10:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FA TIG UE  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

2.b Symptom:

Date	Location	User	Value	Reason
Dec-30-2020 10:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Jan-11-2021 15:49:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-30-2020 10:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HE AD AC	Initial Entry

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

			HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: Not Done	
Jan-11-2021 15:49:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HE AD AC HE  Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Transcription Error
Dec-30-2020 10:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HE AD AC HE  Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

2.c Symptom:

Date	Location	User	Value	Reason
Dec-30-2020 10:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry
Jan-11-2021 15:49:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Dec-30-2020 10:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> CH ILL S  Were fever or systemic sym Not ptoms present on the last d Do ay the Subject Diary was c ne ompleted?:	Initial Entry
Jan-11-2021 15:48:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> CH IL LS  Were fever or systemic sym ptoms present on the last d ay the Subject Diary was co mpleted?:	Transcription Error

090177e196ae3ff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Dec-30-2020 10:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> CH IL LS <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry
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2.d Symptom:

Date	Location	User	Value	Reason
Dec-30-2020 10:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Jan-11-2021 15:48:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-30-2020 10:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> VO MIT ING <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> Not Done	Initial Entry

090177e196ae3ff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Jan-11-2021 15:48:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b>  VO MIT ING  <b>Were fever or systemic sy mptoms present on the las t day the Subject Diary wa s completed?:</b>	Transcription Error
Dec-30-2020 10:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b>  VO MIT ING  <b>Were fever or systemic sy NO mptoms present on the las t day the Subject Diary wa s completed?:</b>	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Dec-30-2020 10:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Jan-11-2021 15:48:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-30-2020 10:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
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090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p><b>Symptom::</b> DIA RR HE A</p> <p><b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> Not Done</p>	Initial Entry
Jan-11-2021 15:48:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p><b>Symptom::</b> DIA RR HE A</p> <p><b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b></p>	Transcription Error
Dec-30-2020 10:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p><b>Symptom::</b> DIA RR HE A</p> <p><b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO</p>	Initial Entry

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

2.f Symptom:

Date	Location	User	Value	Reason
Dec-30-2020 10:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry
Jan-11-2021 15:48:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Dec-30-2020 10:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> NEW OR WORSEN ED MUS CLE PAI N  Were fever or system Not Done ic symptoms present on the last day the Su bject Diary was com pleted?:	Initial Entry
Jan-11-2021 15:48:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> NEW OR WORSEN ED MUS CLE PAI N	Transcription Error

090177e196ae3ff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
Dec-30-2020 10:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE ED MUS CLE PAI N  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Dec-30-2020 10:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSE NED MUS CLE PAI N	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Jan-11-2021 15:48:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-30-2020 10:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.h

Date	Location	User	Value	Reason
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090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)



**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED JOI NT PAIN <b>Were fever or systemi</b> Not Done <b>c symptoms present o</b> <b>n the last day the Sub</b> <b>ject Diary was comple</b> <b>ted?:</b>	Initial Entry
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Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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2.h				
Date	Location	User	Value	Reason
Jan-11-2021 15:47:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED JOI NT PAIN  <b>Were fever or system  ic symptoms present  on the last day the Su  bject Diary was com  pleted?:</b>	Transcription Error
Dec-30-2020 10:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED JOI NT PAIN  <b>Were fever or system NO  ic symptoms present  on the last day the Su  bject Diary was com  pleted?:</b>	Initial Entry

090177e196ae3ff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

2.h Symptom:

Date	Location	User	Value	Reason
Dec-30-2020 10:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENERD JOINT P AIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Jan-11-2021 15:47:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-30-2020 10:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Done	Initial Entry
Jan-08-2021 10:34:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Dec-30-2020 10:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Jan-08-2021 10:34:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-30-2020 10:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> RE DN ESS  <b>Were injection site reactions present on the last day that the Subject Diary was completed?:</b> Not Don	Initial Entry
Jan-11-2021 15:47:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> RE DN ESS  <b>Were injection site reactions present on the last day that the Subject Diary was completed?:</b>	Transcription Error
Dec-30-2020 10:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> RE DN ESS  <b>Were injection site reactions present on the last day that the Subject Diary was completed?:</b> NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-30-2020 10:22:19 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> REDNESS	Initial Entry

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Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Time (US & Canada)	(b) (4), (b) (6)
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5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry
Jan-11-2021 15:47:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Dec-30-2020 10:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <b>Injection Site Reaction::</b> SWE LLI NG  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> Not Done	Initial Entry
Jan-11-2021 15:47:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <b>Injection Site Reaction::</b> SWE LLI NG  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b>	Transcription Error
Dec-30-2020 10:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <b>Injection Site Reaction::</b> SWE LLI NG	Initial Entry

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Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

			Were injection site reactions present on the last day the Subject Diary was completed?:	
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**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Dec-30-2020 10:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> SWELLING	Initial Entry

**5.b Were injection site reactions present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry
Jan-11-2021 15:47:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Dec-30-2020 10:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction PAIN A :: T INJE CTION SITE  Were injection site reactions present on the last day the Subject Diary was completed?: Not Done	Initial Entry
Jan-11-2021 15:47:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction PAIN A :: T INJE	Transcription Error

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

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			CTION SITE	
			Were injection site reactions present on the last day the Subject Diary was completed?:	
Dec-30-2020 10:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Injection Site Reaction PAIN AT INJECTION SITE  Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-30-2020 10:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-11-2021 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Jan-11-2021 15:47:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-30-2020 10:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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Form Status: Data Complete, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

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**1. Data Origin**

Date	Location	User	Value	Reason
Mar-11-2021 14:42:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry
Mar-11-2021 14:42:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Jan-11-2021 15:49:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Mar-11-2021 14:42:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry
Mar-11-2021 14:42:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Jan-11-2021 15:49:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-11-2021 14:44:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-11-2021 14:42:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct

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Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

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				as appropriate.
Mar-11-2021 14:42:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/24/2021	Initial Entry
Mar-11-2021 14:42:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Jan-11-2021 15:49:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Mar-11-2021 14:42:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Jan-11-2021 15:49:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Mar-11-2021 14:44:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BHVTCV	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Mar-11-2021 14:44:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BHVTCV	Initial Entry

**5.b**

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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Form Status: Data Complete, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Mar-11-2021 14:45:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BJ3D1N	Initial Entry
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**5.b Sample ID**

Date	Location	User	Value	Reason
Mar-11-2021 14:45:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BJ3D1N	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Mar-11-2021 14:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BJ3D1P	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Mar-11-2021 14:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BJ3D1P	Initial Entry

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**Header Text:** c4591001

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**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Date	Location	User	Value	Reason
Dec-17-2020 09:54:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Date	Location	User	Value	Reason
Dec-17-2020 09:56:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

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Date	Location	User	Value	Reason
Dec-17-2020 09:57:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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Date	Location	User	Value	Reason
Dec-18-2020 12:55:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Changed Information
Dec-17-2020 09:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

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Date	Location	User	Value	Reason
Dec-17-2020 12:26:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Form Created	

Header Text: c4591001

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Subject No: 11201350

Generated By: (b) (4)

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Form Status: Data Complete

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

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**1. Category:**

Date	Location	User	Value	Reason
Dec-17-2020 09:54:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Dec-17-2020 09:54:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Jan-27-2021 20:31:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Samuel Dychter (b) (4)	Query 2: Clos ed	Response satisfies query
Jan-22-2021 09:10:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Ans wered	yes
Jan-20-2021 20:10:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Samuel Dychter (b) (4)	Query 2: Open ed	GPD Clin: Was this associated with the SAE of the infection?
Dec-17-2020 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Clos ed	Discrepancy has been closed.
Dec-17-2020 14:10:13	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	New Information

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Subject No: 11201350

Generated By: (b) (4)

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Form Status: Data Complete

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

(UTC-05:00) Eastern Time (US & Canada)				
Dec-17-2020 14:10:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WOUND PUMP DRAINAGE	New Information
Dec-17-2020 12:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify WOUND PUMP as follows...Term is unclear. Are you reporting WOUND DRAINAGE? Or VACUUM ASSISTED WOUND CLOSURE? Or other? Please update the verbatim term to clarify. Thank you.
Dec-17-2020 09:54:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WOUND PUMP	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-17-2020 09:54:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/7/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-17-2020 09:54:45 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3ff\Final\Final On: 01-Apr-2021 05:27 (GMT)

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Subject No: 11201350

Generated By: (b) (4)

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Form Status: Data Complete

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

Time (US & Canada)	(b) (4), (b) (6)
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6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-17-2020 09:54:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Dec-17-2020 09:54:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Dec-17-2020 09:54:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Dec-17-2020 09:54:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  If Other, specify:  UNKNOWN	Initial Entry

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1120

Subject No: 11201350

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-17-2020 09:54:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-17-2020 09:54:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-17-2020 09:54:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Dec-17-2020 09:54:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERING/RESOLVING	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Dec-17-2020 09:54:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Category:**

Date	Location	User	Value	Reason
Dec-17-2020 09:56:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Dec-17-2020 09:56:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Dec-17-2020 09:56:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PACE MAKER BATTERY CHAR GE	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Dec-17-2020 09:56:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/17/2020 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Dec-17-2020 09:56:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Nov/17/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
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090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Dec-17-2020 09:56:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Dec-17-2020 09:56:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Dec-17-2020 09:56:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Dec-17-2020 09:56:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  If Other, specify:  HISTORY PACE MAKER	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-17-2020 09:56:06 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

090177e196ae3ff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Site Name: (1120) Meridian Clinical Research

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Time (US & Canada)	(b) (4), (b) (6)
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**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Dec-17-2020 09:56:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Dec-17-2020 09:56:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Dec-17-2020 09:56:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERED/RESOLVED	Initial Entry

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Dec-17-2020 09:56:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1120

Subject No: 11201350

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Category:**

Date	Location	User	Value	Reason
Dec-17-2020 09:57:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Dec-17-2020 09:57:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Dec-17-2020 09:57:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HEMATOMA	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Dec-17-2020 09:57:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/23/2020 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Dec-17-2020 09:57:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Nov/23/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
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090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

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Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Dec-17-2020 09:57:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 3	Initial Entry
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**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

*Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).*

Date	Location	User	Value	Reason
Dec-17-2020 09:57:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**8. Is this adverse event the result of a study Medication Error?**

**If Yes, record the type of medication error on the Medication Error Log.**

Date	Location	User	Value	Reason
Dec-17-2020 09:57:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Dec-17-2020 09:57:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatment( s), this event is due to:  OTHER  <i>If Other, specify:</i>  UNKNOWN	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Dec-17-2020 09:57:06 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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**Form Status:** Data Complete, Frozen

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

Time (US & Canada)	(b) (4), (b) (6)
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**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Dec-17-2020 09:57:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Dec-17-2020 09:57:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Dec-17-2020 09:57:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED WITH SEQUELAE	Initial Entry

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Dec-17-2020 09:57:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

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**1. Category:**

Date	Location	User	Value	Reason
Dec-17-2020 09:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Dec-17-2020 09:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Dec-21-2020 13:06:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Clos ed	The query will be placed on different form
Dec-17-2020 14:04:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 2: Clos ed	Discrepancy has been closed.
Dec-17-2020 12:21:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Ans wered	Changed Information
Dec-17-2020 12:21:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	Changed Information

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**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Deleted

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

Dec-17-2020 12:21:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SUTURE SIT E INFECTIO N	Changed Information
Dec-17-2020 11:50:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 2: Ope ned	Multiple actions for SUTURE SITE INFECTION AND PACEMAKER REMOVAL: Split the term into SUTURE SITE INFECTION and PACEMAKER REMOVAL and report as separate entries and also clarify PACEMAKER REMOVAL whether reporting CARDIAC PACEMAKER REMOVAL or GASTRIC PACEMAKER REMOVAL or other and update the term as appropriate. Thank you.
Dec-17-2020 10:20:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Ope ned	Clinical_ Per report, the subject was hospitalized. However, information on workup

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Subject No: 11201350

Generated By: (b) (4)

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Form Status: Data Complete, Deleted

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

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\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

				(including Covid testing) and treatment with antibiotics are not described. Kindly provide information in a FU report. Thank you.
Dec-17-2020 09:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SUTURE SITE INFECTION AND PACE MAKER REMOVAL	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-17-2020 09:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/3/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-17-2020 12:28:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Changed Information
Dec-17-2020 09:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Dec/8/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-17-2020 09:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

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Subject No: 11201350

Generated By: (b) (4)

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Form Status: Data Complete, Deleted

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Dec-17-2020 09:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Dec-17-2020 09:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Dec-17-2020 09:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  If Other, specify:  UNKNOWN	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-17-2020 09:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

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Form Status: Data Complete, Deleted

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Subject Initials: ---

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\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-17-2020 09:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-17-2020 09:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Dec-18-2020 02:05:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed as data updated.
Dec-17-2020 12:28:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Dec-17-2020 12:21:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE SUTURE SITE INFECTION : Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Dec-17-2020 10:00:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	THIS IS CORRECT
Dec-17-2020 09:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE SUTURE SITE INFECTION AND PACEMAKER REMOVAL: Response to "What was the outcome of this

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**Header Text:** c4591001

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**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Deleted

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

				adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Dec-17-2020 09:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERING/RESOLVIN G	Initial Entry

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Dec-17-2020 09:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Category:**

Date	Location	User	Value	Reason
Dec-17-2020 12:26:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Dec-17-2020 12:26:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Jan-27-2021 19:51:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 4: Closed	Response satisfies query
Jan-26-2021 09:29:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	New Information
Jan-26-2021 09:29:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 3: Deleted	New Information
Jan-26-2021 09:29:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Postoperative wound inf ection to left upper chest	New Information
Jan-25-2021 19:48:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 4: Opened	ClinQuery: Postoperative wound infection: please can you update to include the anatomical location of this AE? Thank you

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1120

Subject No: 11201350

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

Jan-24-2021 20:59:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Candi date	pending Clinical review
Jan-22-2021 16:55:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Closed	No information about antibiotics has been noted on safety report. Issue will be escalated.
Jan-22-2021 09:34:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Changed Information
Jan-22-2021 09:34:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Postoperative wound inf ection	Changed Information
Jan-21-2021 03:33:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	SAE RECON:AER#2020492747,the term in AE CRF was updated to 'automatic implantable cardioverter-defibrillator generator infection while retained as Suture site infection in SDB.Please confirm.If safety update is required, please submit a ffup form.
Jan-15-2021 10:59:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Jan-15-2021 10:59:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> automatic implantable ca rdioverter-defibrillator g enerator infection	Changed Information
Dec-23-2020 18:50:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Reissued:Open ed	Thanks for confirming. Please respond to the query once additional information is available. Thanks
Dec-23-2020 10:46:13 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Information was not provided awaiting medical records

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

Time (US & Canada)				
Dec-22-2020 06:14:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-21-2020 13:08:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Opened	Clinical_ Per report, the subject was hospitalized. However, information on workup (including Covid testing) and treatment with antibiotics are not described. Kindly provide information in a FU report. Thank you.
Dec-18-2020 12:54:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SUTURE SITE INFECT ION	Changed Information
Dec-18-2020 08:59:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	PER WUERY
Dec-18-2020 08:59:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SUTURE SITE INFECT ION (PACEMAKER RE MOVAL)	PER WUERY
Dec-18-2020 07:22:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2020492747,the term was reported as 'Suture site infection (Pace maker removal)in Safety database however, Pacemaker removal only in AE CRF.Per CRF completion guidelines,pls avoid use of a procedure for the AE event name. Please confirm
Dec-17-2020 12:26:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PACEMAKER REMOV AL	Initial Entry

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Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1120

Subject No: 11201350

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-24-2020 11:09:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-23-2020 10:48:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Dec-23-2020 10:48:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/23/2020 UNK:UNK	Changed Information
Dec-22-2020 06:18:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2020492747 ,onset date was recorded as 23Nov2020 in Safety database however, recorded as 03Dec2020 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Dec-17-2020 12:26:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/3/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-17-2020 12:29:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Changed Information
Dec-17-2020 12:26:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Dec/8/2020 UNK:UNK	Initial Entry

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Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-17-2020 12:26:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Dec-18-2020 07:19:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-17-2020 12:26:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE PACEMAKER REMOVAL: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-17-2020 12:26:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or bir th defect?  NO  Did this serious event result in death?  NO  Did this serious event require or prolong hospitalization?	Initial Entry

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1120

Subject No: 11201350

Generated By: (b) (4)

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Form Status: Data Complete

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

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			YES	
			Did this serious event result in persistent or significant disability/incapacity?	
			NO	
			Is this serious event life threatening?	
			NO	
			Other medically important serious event	
			NO	

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Dec-17-2020 12:26:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-15-2021 11:00:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  Pacemaker replacement	Changed Information
Dec-31-2020 03:30:36 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1120

Subject No: 11201350

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

Time (US & Canada)				
Dec-28-2020 10:52:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-23-2020 10:46:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Dec-23-2020 10:46:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Dec-23-2020 10:46:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study tr eatment(s), this event is d ue to:  OTHER  <i>If Other, specify:</i>  unknown	Changed Information
Dec-22-2020 06:16:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2020492747 ,causality was recorded as RELATED in Safety database but was recorded as RELATED in AE CRF. Please confirm correct causality. If safety update is required, please submit a follow-up form.
Dec-21-2020 06:56:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sohil Patel (b) (4)	Query 1: Opened	ClinQuery: Please explain why do you consider this AE related to study medication
Dec-17-2020 12:26:16 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RELATED	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Time (US & Canada)

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-17-2020 12:26:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-17-2020 12:26:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-17-2020 12:26:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Dec-17-2020 12:29:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-17-2020 12:26:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE PACEMAKER REMOVAL: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Dec-17-2020 12:26:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERING/RESOLVING	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Dec-17-2020 12:26:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Dec-18-2020 07:19:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2020492747	Initial Entry

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**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Feb/02/2021

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-02-2021 13:07:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/2/2021	Initial Entry

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Feb/02/2021

**Form:** UNPLANNED VISIT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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*I. Assessments*

Date	Location	User	Value	Reason
Feb-02-2021 13:07:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-02-2021 13:07:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Feb-02-2021 13:07:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CONTACT OUTCOME	Initial Entry

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Feb/02/2021

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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**1. Contact Type:**

Date	Location	User	Value	Reason
Feb-02-2021 13:07:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Feb-02-2021 13:07:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Contact:  Feb/2/2021  Contact Outcome:  VISIT NOT REQUIRED, INV ESTIGATOR DECISION	Initial Entry

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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***1. Date of Completion/Discontinuation/Death :***

Date	Location	User	Value	Reason
Mar-12-2021 09:01:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/24/2021	Initial Entry
Mar-12-2021 09:01:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Jan-28-2021 00:31:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed as data updated.
Jan-27-2021 09:15:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	updated
Jan-27-2021 09:15:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Jan-27-2021 01:26:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM : Please review and consider to add Form Level comment as Not Applicable on End of Treatment : DISPOSITION - TREATMENT CRF. Else, clarify.
Jan-22-2021 09:09:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	I still can't delete which arm they were vaxed in and if they stayed for 30 mnin after vax. Can you please make this to where I can delete it and enter updated data?
Jan-22-2021 00:56:40 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Please note Vaccination form is

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**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

Time (US & Canada)				not frozen for V2. Kindly consider to click on that item and then update data as appropriate. Thank you.
Jan-21-2021 13:45:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	I still can't erase the date of vax and time.
Jan-20-2021 17:01:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Visit 2 is unfrozen.
Jan-20-2021 15:47:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	PLEASE UNLCK VISIT 2 SO THAT I CAN UPDATE IT
Jan-19-2021 00:09:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly consider to update this form if require else mark as Not applicable by selecting form level comment. Thank you.
Jan-15-2021 08:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Jan-04-2021 08:54:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/7/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Mar-12-2021 09:01:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry
Mar-12-2021 09:01:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Initial Entry

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Jan-27-2021 09:15:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Jan-15-2021 08:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Jan-04-2021 08:54:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-12-2021 09:01:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : COM PLET ED	Initial Entry
Mar-12-2021 09:01:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> :	Initial Entry
Jan-27-2021 09:15:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : Not A pplica ble	Initial Entry
Jan-15-2021 16:00:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Clo sed	Auto closed by Validation Check: VC_DS001_23
Jan-15-2021 08:26:08 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	Transcription Error

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

(US & Canada)				
Jan-15-2021 08:26:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> :	Transcription Error
Jan-15-2021 05:41:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6842098;Status on the Disposition - Treatment form is COMPLETED but at least one Dose Date is missing. Please review and update as appropriate.
Jan-04-2021 08:54:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : COMPLETED	Initial Entry

**4. Specify Status:**

Date	Location	User	Value	Reason
Mar-12-2021 09:01:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Jan-27-2021 09:15:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1120

**Site Name:** (1120) Meridian Clinical Research

**Subject No:** 11201350

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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*I. Date of Visit*

Date	Location	User	Value	Reason
Mar-02-2021 04:21:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clos ed	Form updated.
Mar-01-2021 15:10:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	DISPOSITION FORM IS COMPLETE
Feb-26-2021 18:31:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Ope ned	DMW7479110;DOV is entered for Revax Contact but Disposition Treatment at END_OF_TRT visit is null. Please review and update as appropriate.
Feb-26-2021 10:12:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/12/ 2021	Initial Entry

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)



**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form Version:** 10-Dec-2020 02:25

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit  
Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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*1. Select appropriate response - Is participant willing to return for Vaccination 3?*

Date	Location	User	Value	Reason
Feb-26-2021 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-26-2021 10:13:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-26-2021 10:13:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willing to return f or Vaccination 3 Participant is:  eligible and NOT confirmed to have received only placeb o at Vaccination 1/2	Initial Entry

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Feb-26-2021 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/12/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Feb-26-2021 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** WITHDRAWAL OF CONSENT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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***1. Withdrawal of Consent Date :***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Feb-26-2021 11:36:46 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<u><b>Data Entry:</b></u> Not Done	Initial Entry

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** DEATH DETAILS CODED - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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*1. Date of Collection / Notification of Death:*

Date	Location	User	Value	Reason
Feb-26-2021 11:36:59 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1120

Subject No: 11201350

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Subject Status**

Date	Location	User	Value	Reason
Mar-12-2021 09:01:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Jan-15-2021 08:26:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Transcription Error
Jan-04-2021 08:54:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Oct-21-2020 08:33:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Oct-21-2020 08:12:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Mar-12-2021 09:01:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Feb/24/2021	Initial Entry
Feb-15-2021 04:07:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-12-2021 08:40:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	subject reported covid symptoms but per investigators decision a visit is not required
Feb-12-2021 01:57:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	RQ1: Response does not resolve the query. Please review and confirm subject reported "Yes" in Illness

090177e196ae3fff\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

				ediary however no COVID Illness visit is reported in the database.
Feb-11-2021 15:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	because visit is not required
Feb-07-2021 15:03:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Illness eDiary: Subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 02FEB2021. But there is no COVID Illness visit reported in the database. Please clarify.
Jan-15-2021 08:26:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/20/2020	Transcription Error
Jan-15-2021 08:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/20/2020	Transcription Error
Jan-04-2021 08:54:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Dec/7/2020	Initial Entry
Dec-18-2020 07:17:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-17-2020 10:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	UPDATED
Dec-17-2020 08:42:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020492747 Suture site infection (Pace maker removal)(onset date:03Dec2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a

090177e196ae3ff\Final\Final On: 01-Apr-2021 05:27 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1120

**Subject No:** 11201350

**Generated By:** (b) (4)

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1120) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

				follow-up SAE Form.
Oct-21-2020 08:33:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/20/2020	Initial Entry
Oct-21-2020 08:12:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/20/2020	Initial Entry

090177e196ae3ff\Final\Final On: 01-Apr-2021 05:27 (GMT)